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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Informed Consent Action Network, Plaintiff, v. National Institutes of Health, Defendant.	CV-20-01277-PHX-JJT **DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AS TO REQUEST 54464**

The National Institutes of Health ("NIH") submits this Motion for Summary Judgment pursuant to Fed. R. Civ. P. 56. This motion is supported by a Memorandum of Points and Authorities, Statement of Facts, and all matters of record.

MEMORANDUM OF POINTS AND AUTHORITIES

Informed Consent Action Network ("ICAN") has sued NIH under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), over 13 FOIA requests submitted between March 27 and May 22, 2020. Dkt. 1. At issue is NIH's response to one request, which sought "safety and efficacy data and information" regarding the Phase I clinical trial of the mRNA-1273 vaccine[1] currently being developed to combat the SARS-COV-2 Infection ("COVID-19"). On August 13, 2020, NIH issued a response explaining that the National Institute of

[1] *See* Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19), *available at* https://clinicaltrials.gov/ct2/show/NCT04283461 (last visited Nov. 20, 2020).

Allergy and Infectious Diseases ("NIAID"), to which the request was addressed, did not possess responsive information as to efficacy data because the Phase I trial tests the safety, not efficacy, of the vaccine. NIH also explained it was withholding safety information in full pursuant to FOIA's Exemption 4, 5 U.S.C. § 552(b)(4). However, NIH recently learned that the manufacturer of the vaccine was going to make the safety information publicly available. Thus, NIH has released the safety information, with patient information redacted pursuant to FOIA's Exemption 6, 5 U.S.C. § 552(b)(6).

ICAN challenges the adequacy of the search and the propriety of the Exemption 6 redactions. Summary judgment in favor of NIH is proper because it adequately searched for responsive records and properly redacted those documents pursuant to Exemption 6.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. COVID-19 and NIH's Response to the Pandemic.

COVID-19, a disease caused by a novel strain of coronavirus (SARS-CoV-2), was declared by the World Health Organization to be a global pandemic on March 11, 2020.[2] As of November 20, 2020, over 11.7 million people in the United States had tested positive for the virus. *See* https://coronavirus.jhu.edu/map.html (last visited November 20, 2020). Tragically, the United States holds the world record for the highest number of cases and deaths (252,599) due to COVID-19. *Id.*

NIH has been at the forefront of responding to this pandemic. As the nation's medical research agency, it is made up of 27 different components, each of which has its own research agenda. Def. Statement of Facts ("DSOF"), ¶ 1. NIH views COVID-19 as potentially "the greatest public health crisis of our generation" and has "mounted a vigorous research response" to "address the unprecedented challenge that [COVID-19] poses to our health and economy." *See* Ex. 3, NIH Strategic Plan, at 3.

Component NIAID leads research to better understand, treat, and ultimately prevent infectious diseases such as COVID-19. DSOF, ¶ 2. To that end, NIAID has sponsored a

[2] *See* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

study called "Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults ("Phase I")." DSOF, ¶¶ 4-9. Phase I is a clinical trial designed to assess the safety of the mRNA-1273 vaccine manufactured by ModernaTX, Inc. ("Moderna"), a private biotechnology company. DSOF, ¶¶ 4-5. Phase I will evaluate different doses of the vaccine for safety and the doses' ability to induce an immune response in study volunteers. *Id.* The study began on March 16, 2020 and is estimated to be completed by November 22, 2021. *Id.* As of May 25, 2020, 85 patients had been enrolled in the Phase I study. *Id.*

Although NIAID sponsors Phase I, Kaiser Permanente and Emory University actually conducted the trial at their non-NIH locations prior to June 2, 2020. DSOF, ¶ 9. NIH neither owned nor housed the raw data for Phase I during this time period. DSOF, ¶ 10. Raw data consists of unprocessed data that has not been statistically analyzed. *Id.* Examples of raw data include gender, age, records of original observations, measurements and activities like lab notes, evaluations, data recorded by instruments, and researchers' records of subjects/patients (such as patient medical charts, hospital records, X-rays, attending physician's notes, etc). *Id.* Phase I raw data are entered into a system managed by the independent Statistical and Data Coordinating Center (SDCC). *Id.* Actual source documents are maintained where the clinical trials are conducted, unless directly captured into the SDCC system, which would then serve as the actual source. *Id.*

On June 2, 2020, SDCC sent NIAID a safety report it had prepared regarding the Phase I trial. DSOF, ¶ 28. This report provided information on "the study of 85 subjects enrolled and vaccinated as of May 25, 2020." DSOF, ¶ 40, Attach. E at p. 1.

B. ICAN and Its FOIA Requests.

Since May 2019, ICAN has submitted at least 27 FOIA requests to the U.S. Department of Health and Human Services, the vast majority of which are directed at NIH and its components. DSOF, ¶ 11, Ex. 1, ¶ 7. At present, NIH has completed almost half of ICAN's FOIA requests, notwithstanding the fact that NIH has experienced a dramatic and unprecedented increase in the number of FOIA requests received since the pandemic began.

Id. At present, NIH is facing an approximately 50% increase in FOIA requests in Fiscal Year 2020 (FY2020), as compared to Fiscal Year 2019 (FY2019). *Id.*

In its Complaint, ICAN identified 13 FOIA requests. Of those requests, NIH continues to process eight and has closed five. A summary is provided below:

REQUEST NUMBER	Dated	Status
Request 53821	3/27/20	Completed
Request 53822	3/27/20	Pending
Request 53826	3/27/20	Completed
Request 53963	4/9/20	Pending
Request 53962	4/9/20	Pending
Request 53961	4/9/20	Pending
Request 53958	4/9/20	Completed
Request 53960	4/9/20	Pending
Request 53959	4/9/20	Pending
Request 54105	4/29/20	Completed
Request 54106	4/29/20	Pending
Request 54107	4/29/20	Pending
Request 54464	5/22/20	Completed – ICAN is challenging response

See Dkt. 1-1 at 3-40; DSOF, Ex. 1, ¶ 8.

As to the closed requests, NIH released 181 pages in response to Request 53821; closed Request 53826 as duplicative of a prior request to which it had already fully responded; explained that no records were found with respect to Requests 53958 and 54105 because the individuals identified in the requests were not NIH employees during the requested time period; and closed Request 54464 after determining there were no responsive records as to efficacy data, while withholding in full 1,093 pages of safety records under Exemption 4. *Id.* NIH subsequently released the safety records with Exemption 6 redactions. DSOF, ¶¶ 32-35. It is NIH's response to the last request—Request 54464—that ICAN currently challenges.

C. NIH's Response to Request 54464.

On May 22, 2020, ICAN submitted Request 54464, seeking:

> **All safety and efficacy data and information regarding mRNA-1273, including from the Phase I clinical trial of this experimental vaccine conducted by [NIAID].**

DSOF, ¶ 11. On June 8, 2020, NIH sent Plaintiff a formal acknowledgment letter regarding Request 54464. DSOF, Ex. 1, ¶ 10. On July 13, 2020, NIH received a letter from Moderna objecting to the release of a 1,093-page Safety Summary Report ("Report").[3] DSOF, ¶¶ 31-32. Moderna asserted that the "Report contains detailed safety information from Phase I clinical trials for the Moderna-manufactured 2019-nCoV vaccine (mRNA-1273) conducted pursuant to a Clinical Trial Agreement ("CTA") . . . between Moderna and the Division of Microbiology and Infectious Diseases . . ., National Institute of Allergy and Infectious Diseases ("NIAID")." *Id.*, Attach. C. Moderna objected to the disclosure of the Report "because it contains Moderna's trade secrets and confidential commercial information, which is subject to FOIA Exemption 4 and is prohibited from disclosure under the Trade Secrets Act, 18 U.S.C. § 1905." *Id.* Accordingly, Moderna asked that NIH withhold the Report in its entirety. *Id.*

On August 13, 2020, NIH issued a response letter to ICAN, stating that, as to the request for efficacy data, the "purpose of a Phase I trial is to establish safety. Thus, NIAID has access to safety data, but no efficacy data." DSOF, ¶ 32. In addition, NIH stated that it was withholding 1,093 pages of safety information pursuant to Exemption 4. *Id.* However, in late October 2020, NIH learned that Moderna was making the Report publicly available (with minor redactions) and that Moderna expressly withdrew its objections to the release of the information. DSOF, ¶ 33. Thus, on October 29 and November 9, 2020, NIH released the Report while redacting some portions pursuant to Exemption 6. DSOF ¶ 34. On November 20, 2020, NIH re-released the Report after determining that some redactions had been

[3] *See* 45 C.F.R. 5.42 regarding predisclosure notification process for confidential commercial information.

inadvertently been applied, and therefore removing them. DSOF, ¶ 35.

II. STANDARD OF REVIEW

A court reviews an agency's response to a FOIA request *de novo*. 5 U.S.C. § 552(a)(4)(B). "As a general rule, all FOIA determinations should be resolved on summary judgment." *Lawyers' Comm. for Civil Rights of San Francisco Bay Area v. U.S. Dep't of the Treasury ("Lawyers' Comm.")*, 534 F. Supp. 2d 1126, 1131 (N.D. Cal. 2008) (citing *Nat'l Wildlife Fed'n v. U.S. Forest Serv.*, 861 F.2d 1114 (9th Cir. 1998)).

III. ARGUMENT

To obtain summary judgment in a FOIA case, the agency must show it conducted an adequate search for records, *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985), and that any withheld documents are statutorily exempt from disclosure. *Willamette Indus., Inc. v. United States*, 689 F.2d 865, 868 (9th Cir. 1982). NIH satisfies both elements.

A. NIH's Search For Records Was Adequate.

FOIA requires agencies to search for responsive records, which means "to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request." 5 U.S.C. § 552(a)(3)(D). "In evaluating the sufficiency of an agency's search, the issue to be resolved is not whether there might exist any other documents possibly responsive to the request, but rather whether the search for those documents was adequate." *Lahr v. Nat'l Transp. Safety Bd.*, 569 F.3d 964, 973 (9th Cir. 2009) (internal citation omitted); *Iturralde v. Comptroller of the Currency*, 315 F.3d 311, 315 (D.C. Cir. 2003) ("adequacy of a FOIA search is generally determined not by the fruits of the search, but by the appropriateness of the methods used to carry out the search"). An agency's search is adequate if it was "reasonably calculated to uncover all relevant documents." *Zemansky*, 767 F.2d at 571. In addition, "reasonably detailed, nonconclusory affidavits submitted in good faith" are generally sufficient to demonstrate the adequacy of the agency's search. *Id.* Affidavits or declarations that describe what records were searched, by whom, and through what processes, are accorded "a presumption of good faith, which cannot be rebutted by purely speculative claims about the existence and discoverability of other documents." *Lawyers'*

Comm., 534 F. Supp. 2d at 1131 (citing *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991)).

Here, NIH's search for responsive records was adequate. Its FOIA Officer's declaration details the steps taken to search for responsive records. DSOF, Ex. 1, ¶¶ 16-29. NIH sent Request 54464 to NIAID on or around May 22, 2020. DSOF ¶ 11. It did so because the request expressly named NIAID and because NIAID is the component that houses records related to "mRNA-1273" and "Phase I." DSOF ¶ 12.

NIAID first sent the request to its Vaccine Research Center (VRC), and asked it to begin a search for potentially responsive records. DSOF, ¶ 13. VRC responded that it did not have any responsive records because it is does not sponsor the mRNA-1273 clinical trial and does not hold or own any such data. *Id.* VRC advised however that Request 54464 should instead be directed to DMID because that is the entity involved in the mRNA-1273 clinical trial. *Id.* VRC further stated that the NIH point of contact was the DMID official in charge of the vaccine program, and that he would be in the best position to assess and search for records responsive to Plaintiff's request. *Id.* As a result, NIAID FOIA Office sent the search request to DMID on June 2, 2020. DSOF, ¶ 14.

Dr. Christopher Roberts, Viral Pathogens Clinical Research Program Officer, is the official in charge of the DMID vaccine program. DSOF, ¶ 15. NIAID FOIA Office asked him to search his electronic files and emails for records related to safety data for "mRNA-1273" and "Phase I." *Id.* Dr. Roberts' work computer contained information related to all the grants he oversees, one of which is the clinical trial funded by NIAID for "mRNA-1273" and "Phase I." DSOF, ¶ 15.

DMID and Dr. Roberts searched his files by using the following keywords: "mRNA-1273", "Phase I", "Moderna", "DMID 20-003" and "safety data reports." DSOF, ¶ 18. The keywords "mRNA-1273" and "Phase I" were utilized because Request 54464 specifically included them and because those terms would allow for a broad enough search such that one could reasonably expect that responsive information would be captured. DSOF, ¶ 19. The keyword "Moderna" was used because Moderna is manufacturing mRNA-1273. DSOF, ¶ 20.

The keyword "DMID 20-003" was used because DMID is the NIH entity involved in the clinical trial. DSOF, ¶ 21. The keywords "safety data reports" were used because "safety" and "data" were specifically identified in Request 54464 and were specific enough to return potentially responsive records. DSOF, ¶ 22. In addition, Dr. Roberts knew that NIAID would receive a report about the safety study, rather than raw data. *Id.* Therefore, the keywords "safety data report" were appropriate given his expertise. *Id.* As a result of the search, the 1,093-page Safety Summary Report was located. DSOF ¶ 23.

1. The Cut-off Date for the Agency's Search Was June 2, 2020.

Per HHS FOIA regulations, 45 C.F.R. § 5.24(d), the cut-off date for a records search is the date upon which the agency first begins its search, unless the request specifies an earlier cut-off date or a specific date range. DSOF, ¶ 16. Here, Request 54464 did not provide a cut-off date or date range. DSOF, ¶ 17. Also, DMID immediately began working on the search request when it received it on June 2, 2020 from NIAID FOIA Office. *Id.* Thus, the cut-off date for the search for records was up to and including June 2, 2020. *Id.*

2. NIH Did Not Use "Efficacy" as a Search Term Because Phase I Did Not Assess the Efficacy of mRNA-1273 and Because Efficacy Data Was Not Yet Available.

Although Plaintiff sought both safety and efficacy data of the Phase I trial of mRNA-1273, the term "efficacy" was not included in the search, as Phase I did not assess efficacy. DSOF ¶. Before their introduction into an immunization program, vaccines undergo several steps of evaluation to assess their safety and efficacy in clinical trials. DSOF, ¶ 24. A safety report is designed to find possible vaccine safety issues, that is, an outcome or side effect that is believed to have resulted from administering a vaccine. DSOF, ¶ 24. Ex. 1, ¶¶ 22-24. Vaccine efficacy on the other hand, determines whether a vaccine can bring the intended beneficial effects on vaccinated individuals in a defined population under ideal conditions of use. *Id.* Vaccine efficacy is therefore generally not addressed until Phase III of a clinical trial, after Phase I's initial safety stage has been evaluated. *Id.*

As of June 2, 2020, only the initial safety stage of Phase I was underway. DSOF, ¶¶ 24-25. The Phase III clinical trial began on July 27, 2020, after the cut-off date for the

search. *Id.* Ultimately, Phase I was not addressing efficacy, and NIH did not possess records regarding subsequent clinical trial phases at the time of the search because the search occurred before those phases actually began. DSOF ¶¶ 24-28. Thus, the keyword "efficacy" was not used, and no efficacy information was (or could have been) found. *Id.*

3. No Supplemental Searches Were Required.

Furthermore, no supplemental search was conducted because the agency component and the official actually in charge of the mRNA-1273 vaccine program performed the search. DSOF, ¶ 29. Dr. Roberts was the DMID expert on Phase I who was most likely to know of any documents about the trial that the agency possessed. *Id.* Based on his expertise, Dr. Roberts knew that the only data that NIH had on Phase I was within the 1,093-page Report and that his electronic work files were the only place that information was housed. DSOF, ¶ 30. In addition to the above, no other components were asked to conduct a search because no other components would have had additional or different information than the agency official who was actually assigned to handle information pertaining to the Phase I trial of mRNA-1273. DSOF, ¶ 29.

Overall, NIH has demonstrated "'beyond material doubt . . . that it has conducted" an adequate search. *S. Yuba River Citizens League v. Nat'l Marine Fisheries Serv.*, 2008 U.S. Dist. LEXIS 107177, at *35 (E.D. Cal. June 20, 2008) (quoting *Zemansky*, 767 F.2d at 571). NIH's affidavit describes "what records were searched, by whom, and through what process." *Lawyers' Comm.*, 534 F. Supp. 2d at 1131 (citation omitted). Moreover, "[t]he agency is not required to search every record system, but may limit itself to those systems in which it believes responsive records are likely to be located." *ACLU of Ariz. v. DHS*, 2017 U.S. Dist. LEXIS 128518, at * 10, CV-15-00247-PHX-JJT (D. Ariz. Aug. 14, 2017) Such is the case here. By casting a wide net using general terms, consulting with VRC and DMID, and searching the electronic files of the official in charge of the relevant vaccine program, NIH conducted a reasonable search of the components most likely to have the requested information and searched all files likely to contain responsive materials.

In challenging the adequacy of the search, ICAN questions "whether NIH is in

possession of (i) **any** efficacy or immunogenicity data regarding mRNA-1273; and/or (ii) any additional safety data regarding mRNA-1273." Ex. 4 (emphasis in original). These questions, however, do not constitute the standard by which NIH's search may be evaluated. As an initial matter, Request 54644 makes no mention of "immunogenicity" and specifically identifies "Phase I" as the subject of the request. *See* DSOF, Ex. 1, Attach. A. Furthermore, as explained above, NIH does not house or own the raw data pertaining to mRNA-1273 and it would not have had any efficacy data as of the cut-off date for the search at issue. "FOIA cannot be used to request records which the agency may create in the future in the course of carrying out its mission." 45 C.F.R. § 5.24(d). Thus, only records in existence on or before June 2, 2020 are at issue here.

Ultimately, FOIA requires only "a reasonable search for records, not a perfect one." *Hamdan v. DOJ*, 797 F.3d 759, 772 (9th Cir. 2015). On its face, the methods used to conduct the search were reasonably calculated to uncover all relevant documents. Thus, NIH has met is burden under FOIA.

B. NIH Properly Withheld Patient Information Under Exemption 6.

A document may be withheld or redacted "if it falls within one of nine statutory exemptions to the [FOIA] disclosure requirement." *Kamman v. IRS*, 56 F.3d 46, 48 (9th Cir. 1995); *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 687 (9th Cir. 2012) ("FOIA contemplates that some information can legitimately be kept from the public through the invocation of nine 'exemptions' to disclosure."). The Supreme Court has noted that "FOIA expressly recognizes that important interests are served by its exemptions," and that "those exemptions are as much a part of FOIA's purposes and policies as the statute's disclosure requirement." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) (abrogating *Nat'l Parks & Conservation Assn. v. Morton*, 498 F.2d 765 (1974)).

Government agencies ordinarily submit detailed affidavits, commonly referred to as "*Vaughn* Indices," that identify the documents withheld, the FOIA exemptions claimed, and a particularized explanation of why each document falls within the claimed exemption. *Lion Raisins v. U.S. Dep't. of Agric.*, 354 F.3d 1072, 1082 (9th Cir. 2004) (citing *Vaughn v. Rosen*,

484 F.2d 820, 823-25 (D.C. Cir. 1973)). A *Vaughn* Index and the agency's declarations must reasonably describe the documents as well as facts sufficient to establish an exemption. *Kamman*, 56 F.3d at 48. A court accords substantial weight to the agency's affidavits. *Minier v. CIA*, 88 F.3d 796, 800 (9th Cir. 1996).

Exemption 6 "allows an agency to withhold 'personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.'" *Prudential Locations LLC v. Dep't. of Housing and Urban Dev.*, 739 F.3d 424, 429 (9th Cir. 2013) (citing § 552(b)(6)). Its primary purpose is "to protect individuals from the injury and embarrassment that can result from the unnecessary disclosure of personal information." *U.S. Dep't. of State v. Wash. Post Co.*, 456 U.S. 595, 599 (1982). The exemption was "intended to cover detailed Government records on an individual which can be identified as applying to that individual." *Id.* at 602 (citation omitted). The term "similar files" in the exemption has a "broad, rather than a narrow, meaning." *Id.* at 600.

When analyzing Exemption 6, the Court must weigh two competing interests: the individual's right to privacy and the public's right to government information. *U.S. Dep't of the Air Force v. Rose*, 425 U.S. 352, 370-82 (1976). In considering the individual's right to privacy, the first step "is ensuring that disclosure implicates a personal privacy interest that is nontrivial, . . . or, put differently, more than *de minimis*. . . That determination involves assessing both the nature of the privacy interest at stake and the likelihood that disclosure would lead to its invasion." *Yonemoto*, 686 F.3d at 693.

The second step employs a balancing approach, in which "the privacy interests identified in the first step [are placed] on one end of the balance, and the public interest favoring disclosure on the other." *Id.* To do so, the Court examines, first, whether "the public interest sought to be advanced is a significant one," *Yonemoto*, 686 F.3d at 694, and second, whether the "information sought is likely to advance that interest." *Cameranesi v. U.S. Dep't of Def.*, 856 F.3d 626, 637 (9th Cir. 2017) (internal citation omitted). However, "the *only* relevant public interest in the FOIA balancing analysis is the extent to which disclosure of the information sought would she[d] light on an agency's performance of its statutory duties or

otherwise let citizens know what their government is up to." *Id.* (citation omitted, emphasis and brackets in original); *Bibles v. Oregon Nat'l Desert Ass'n*, 519 U.S. 355, 355-56 (1997) (same). Furthermore, "FOIA only recognizes the public's interest in knowing 'what their government is up to' and does not create an avenue to acquire information about other private parties held in the government's files." *Painting Indus. of Hawaii Mkt. Recovery Fund v. U.S. Dep't of the Air Force*, 26 F.3d 1479, 1484 (9th Cir. 1994) (citing *U.S. Dep't of Justice v. Reporters Comm.*, 489 U.S. 749, 772-73 (1989)).

As discussed below, all of the redacted information involves the non-trivial privacy interests of the 85 patients enrolled in the Phase I mRNA-1273 study. Specifically, the redacted information consists of information about non-federal, private parties that is typically treated as confidential and that sheds little to no light on the agency's activities.

1. Patients Enrolled in the Clinical Trial Have a Nontrivial Privacy Interest in the Redacted Information That Outweighs Any Public Interest in the Information.

To fall within the protection of Exemption 6, the privacy interests at stake must be "some nontrivial privacy interest in nondisclosure." *Cameranesi*, 856 F.3d at 637 (9th Cir. 2017) (citation omitted). The interest is not a "cramped notion," *Yonemoto*, 686 F.3d at 693, but rather, is broad and encompasses a range of "concerns relating to an 'individual's control of information concerning his or her person.'" *Lahr*, 569 F.3d at 974 (quoting *Reporters Comm. for Freedom of the Press*, 489 U.S. at 763 (1989)). Indeed, it is enough to demonstrate that the interest is simply more than *de minimus*. *Tuffly v. U.S. Dep't Homeland Sec.*, 870 F.3d 1086, 1092 (9th Cir. 2017). A nontrivial privacy interest is implicated when the disclosure opens the person to possible embarrassment, harassment, or risk of mistreatment. *Cameranesi*, 856 F.3d at 638. NIH redacted limited information that pertains to Phase I patients' personal medical information that was pulled directly from their medical records. In addition, such information provides little to no information as to NIH's performance of its statutory duties.

a. Each Patients' Personal Identification Number Should Be Withheld.

NIH redacted the Subject ID data that appears throughout the Report. DSOF, ¶¶ 37-40, Ex. 1, Attach. E-F; Ex. 2. This data consists of each patient's medical record identification

number. DSOF, 37. It is unique to each patient, and is treated as confidential, private information. DSOF, ¶ 37. If released, the Subject ID could be used to compile medical information specific to each patient. DSOF, ¶ 38. The Subject ID appears in tables summarizing each patient's medical issues and medical history, why a patient may have ended treatment, and medical diagnoses that are pulled directly from the patient's medical records. *Id.* If the personal identifiers were released, information specific to each patient could be aggregated to reveal personal details about the patient's medical records and history. *Id.* Such information clearly implicates a non-trivial privacy interest. *See, e.g., Kubiv v. U.S. Fed. Bur. of Prisons*, 2011 U.S. Dist. LEXIS 71300, at * 27 (D. Or. Jul. 1, 2011) (holding BOP properly withheld information regarding medical conditions and/or treatment of prisoners involved in a riot).

In addition, being able to link specific medical conditions to an individual patient does nothing to inform the public about "what their government is up to." *Painting Indus. of Hawaii Mkt. Recovery Fund*, 26 F.3d at 1484. Of note, the Subject ID numbers are not created or assigned by NIH—rather, the clinical sites create and handle that information. DSOF, ¶ 40. Furthermore, NIH did not provide direct care and treatment to the patients and did not collect the data from each patient; rather Kaiser Permanente and Emory University did. DSOF, ¶¶ 9-10. Thus, this information sheds no light on the acts or omission of the agency itself. *See Lowry v. SSA*, 2001 U.S. Dist. LEXIS 23474, at *35 (D. Or. Aug. 29, 2001) ("Certainly, Lowry is not entitled to any potentially sensitive personal or medical information."); *Whitehouse v. U.S. Dep't of Labor*, 997 F. Supp. 172, 175 (D. Mass. Mar. 9, 1998) (denying FOIA request concerning medical records because there was no practical way to redact potentially identifying patient information). As such, releasing this information would do nothing more than improperly "create an avenue to acquire information about other private parties held in the government's files." *Painting Indus. of Hawaii Mkt. Recovery Fund*, 26 F.3d at 1484. This information is properly redacted.

b. Information Documenting Patients' Medical Diagnoses Should Be Withheld.

NIH redacted information contained in Appendix B under the table heading of

"Adverse Event." DSOF, ¶ 41, Ex. 2. An adverse event is "any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related." *Id.* Such information is written in the patient's medical record by a medical professional at the site. DSOF, ¶ 42. It is a medical diagnosis specific to the patient and drawn directly from that patient's medical record. *Id.* Because the information is about the medical diagnosis of an individual patient that is pulled directly from that patient's medical record, NIH determined that the Adverse Event data implicates a non-trivial privacy interest of the patients enrolled in this study. DSOF, ¶ 43.

Furthermore, release of this information would shed no light on the workings of the NIH. Of note, NIH did not provide direct care and treatment to the patients and did not collect the data from each patient; rather Kaiser Permanente and Emory University did. DSOF, ¶ 44. The content of the Report sheds no light on the acts or omission of the agency itself. *Id.* Moreover, adverse events information was released without redaction in the same table under the heading of "MedDRA Preferred Term." DSOF, ¶ 45. The data in that column is *not* pulled directly from the medical records but rather constitutes the broad technical terms used to categorize the diagnoses. *Id.* In other words, the "MedDRA Preferred Term" provides information about "untoward medical occurrences" while mitigating the risk of linking the information to a specific subject. *Id.*

Yet still, the specific data regarding adverse events was collated, analyzed and detailed in the Report itself, and that information was not redacted. DSOF, ¶ 46. This data allows one to see all documented adverse events, the severity of those events and whether the event was related to the vaccine, while also protecting the privacy of each individual patient. Thus, NIH properly redacted the information from each patient's medical records, while releasing segregable information not drawn directly from those medical records. *Id.*

c. Patient Information Not Related to the Vaccine Should Be Withheld.

NIH withheld information that falls under the table heading of "If Not Related, Alternative Etiology." DSOF, ¶ 48. This column consists of the medical opinion as to the cause of an individual patient's health issues that appears in each patient's medical records.

Id. Specifically, this column contains information about a patient's health condition that is deemed to be unrelated to the vaccine. *Id.* Also, these redactions comply with the industry standard recommendations on anonymizations. DSOF, ¶ 49. Because this information is about the cause of a patient's medical condition and is pulled directly from that patient's medical record, NIH determined that the "If Not Related, Alternative Etiology" data implicates a non-trivial privacy interest of the patients enrolled in this study. DSOF, ¶ 50.

Moreover, because the redacted information talks about conditions *unrelated* to the vaccine, the privacy interest in that information outweighs any potential public interest that might exist. DSOF, ¶ 51. Even if a public interest exists, that information is collated and summarized in the Report in a format that shields the individual patients' privacy. DSOF, ¶ 52. Thus, NIH properly redacted the information, while releasing segregable information not drawn directly from each patients' medical records.

d. NIH Properly Withheld Patients' Individual Ages In Some Tables.

NIH redacted "Age" data in Appendix E. DSOF, ¶ 54. This information gives each patient's exact age, is in a table listing patients who obtained abnormal laboratory results, and is drawn directly from the patient's medical records. *Id.* Given the small sample size of patients in the study (85), this information could be used to identify an actual patient. DSOF, ¶ 55. For these reasons and those reasons described above in the prior categories, NIH determined that the age data implicates a non-trivial privacy interest of the patients enrolled in this study. DSOF, ¶ 56. Furthermore, specific age data appears in the Report in a format that does not reveal any individual patient's private information. DSOF, 57. Thus, NIH properly redacted the information, while releasing segregable information not drawn directly from each patients' medical records.

e. Notes About Patients' Medical Histories Should Be Withheld.

NIH redacted information that appeared under the heading of "Comments" in Appendices B and G. DSOF, ¶ 59. The redacted information consists of medical providers' additional notes on each patient's medical history, including but not limited to, seasonal allergies, hospital visits, identifying skin markings and personal activities. *Id.* This

information is drawn directly from the patient's medical records. *Id.* For these reasons and those reasons described above in the prior categories, NIH determined that the medical information contained in the Comments section implicates a non-trivial privacy interest of the patients enrolled in this study. DSOF, ¶ 60.

In addition, NIH determined that releasing the Comments information would shed no light on the workings of the NIH and does not appear to implicate any public interest. Of note, NIH did not provide direct care and treatment to the patients and did not collect the data from each patient; rather Kaiser Permanente and Emory University did. DSOF, ¶ 61. Moreover, information about the patient's medical condition and adverse event was released without redaction in the same table under the heading of "MedDRA Preferred Term." DSOF, ¶ 62. The data in that column is *not* pulled directly from the medical records but rather constitutes the broad technical terms used to categorize the diagnoses. *Id.* Thus, NIH properly redacted the information, while releasing segregable information not drawn directly from each patients' medical records.

f. Limited Redactions of Deviation Information Are Proper.

NIH withheld some information appearing under the table headings "Reasons for Deviation" and "Deviation Resolution" in Appendices G1-G2. DSOF, ¶ 64. These columns detail why an individual test deviated from the protocol and what steps if any were taken to remedy the deviation. *Id.* The few redactions that were made to these sections applied to information specific to the patient's health condition and personal details that were drawn directly from the patient's medical records. *Id.* Reasons for Deviation redactions were applied to medical annotations about each patient's treatment. *Id.* Deviation Resolution redactions were applied to medical annotations, including observations regarding patients' personal habits and life circumstances, and recommendations made to individual patients. *Id.* Because this data contains information about the medical diagnosis of an individual patient that is pulled directly from that patient's medical record, NIH determined that the personal medical information implicates a non-trivial privacy interest of the patients enrolled in this study. DSOF, ¶ 66.

In addition, NIH determined that releasing the information would shed no light on the workings of the NIH and does not appear to implicate any public interest. DSOF, 67. Of note, NIH did not provide direct care and treatment to the patients and did not collect the data from each patient; rather Kaiser Permanente and Emory University did. *Id.*

Yet still, the specific data pertaining to Reason for Deviation was collated, analyzed and detailed in the Report itself, and that information was not redacted. DSOF, ¶ 68. This data allows one to see all documented protocol deviations across the age groups, while also protecting the privacy of each individual patient. *Id.* Thus, NIH properly redacted the information, while releasing segregable information not drawn directly from each patients' medical records.

IV. CONCLUSION

NIH properly searched for and redacted information responsive to Request 54464 pursuant to Exemption 6. In making limited redactions, NIH weighed the individuals' privacy interest in their personal information against the public interest. The redacted information does not directly reveal the operations or activities of the agency. Therefore, the privacy interests outweigh the public interest, and the information is properly redacted.

Respectfully submitted this 20th day of November 2020.

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2020, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrant(s):

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