EMPOWER OVERSIGHT

Whistleblowers & Research



February 24, 2022

VIA ELECTRONIC TRANSMISSION: gorka.garcia-malene@nih.gov

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VIA ELECTRONIC TRANSMISSION: meghan.loftus@usdoj.gov

Meghan Loftus Assistant United States Attorney Office of the United States Attorney Justin W. Williams U.S. Attorney's Building 2100 Jamieson Ave. Alexandria, VA 22314

RE: FREEDOM OF INFORMATION ACT APPEAL FOIA REQUEST NUMBER 56712

Dear Mr. Garcia-Malene:

INTRODUCTION

With respect to the National Institutes of Health's ("SEC") Freedom of Information Act ("FOIA")¹ Request Number 56712, Empower Oversight Whistleblowers & Research ("Empower

¹ The FOIA is codified at 5 U.S.C. § 552.

Oversight")² appeals the NIH's February 7, 2022, initial determination on the grounds that NIH's FOIA staff:

- Did not perform a search for records that was reasonably calculated to find all responsive records;
- Claimed FOIA Exemption b(5)—specifically for the deliberative process privilege—for records that were not both pre-decisional and deliberative; and
- Claimed FOIA Exemption b(6) for records that do not invoke a legitimate personal privacy interest.

Accordingly, Empower Oversight respectfully requests that the NIH review the nature and scope of its FOIA staff's records search and review, correct any deficiencies that are identified, and apprise Empower Oversight of the results of such review.

BACKGROUND

1. Empower Oversight's July 14, 2021, FOIA Request

On July 14, 2021, Empower Oversight filed with the NIH a request for records under the FOIA.³ Empower Oversight's July 14th FOIA request seeks:

1) All communications regarding the request to post the SARS-CoV-2 [genetic] sequences to the Sequence Read Archive in March 2020. This request covers all communications between March 1, 2020 to March 31, 2020.

2) All communications regarding the request to withdraw the SARS-CoV-2 sequences from Sequence Read Archive in June 2020. This request covers all communications between June 1, 2020 to June 31, 2020.

3) All communications regarding these withdrawn sequences as reported by a preprint titled "Recovery of deleted deep sequencing data sheds more light on the early Wuhan SARS-CoV-2 epidemic" by Jesse Bloom, a virologist at the Fred Hutchinson Cancer Research Center. This request covers all communications between Jesse Bloom and the NIH, from January 1, 2021 and the present. This request all covers all communications inside the NIH regarding the preprint from June 21, 2021 to the present.

² Empower Oversight is a nonpartisan, nonprofit educational organization, which is dedicated to enhancing independent oversight of government and corporate wrongdoing. It works to help insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities, and seeks to hold those authorities accountable to act on such reports by, among other means, publishing information concerning the same.

³ In compliance with the NIH's procedures, which require all requesters to submit their FOIA requests "through [the NIH's] online portal... rather than mail, fax, or courier," Empower Oversight registered with the NIH's online portal, and used it to submit its request. *See*, NIH, *Submitting FOIA Requests* (Last Reviewed on March 27, 2020), available at <u>https://www.nih.gov/institutes-nih/nih-office-director/office-</u> communications-public-liaison/freedom-information-act-office/submitting-foia-requests.

4) All communications to, from, and within the NIH press office about the NIH statement released on June 23, 2021, and about reports that these sequences were removed from the Sequence Read Archive. This includes all emails related to the drafting of the statement, communications about the reported removal, and communications with reporters. This request covers all communications between June 21, 2021 to June 25, 2021.⁴

In addition, Empower Oversight requested: 1) a waiver of search and duplication fees associated with the NIH's processing of its FOIA request, and 2) expedited processing.

In support of its FOIA request, Empower Oversight explained that in March 2020 Chinese researchers submitted SARS-CoV-2 genetic sequences for posting to the NIH's Sequence Read Archive ("SRA"), and in June of 2020 they requested that the same sequences be withdrawn from the SRA.⁵ Genetic sequences of the SARS-CoV-2 virus are critical to understanding how the coronavirus pandemic (which has killed more than 934,000 Americans)⁶ started and how future pandemics can be prevented.⁷ Furthermore, the presence of the SARS-CoV-2 genetic sequences on U.S. government storage resources is crucial because, as the U.S. Department of State has advised, China has not been transparent in connection with efforts to discover the origin of the SARS-CoV-2 virus.⁸ Indeed, China has removed from its own online databases genetic sequences for RaTG13, which is a bat coronavirus that the Wuhan Institute of Virology ("WIV") has studied since at least 2016 and which it claimed to be the closest coronavirus sample to SARS-CoV-2 in January 2020 (RaTG13 is reported to be 96.2% similar to SARS-CoV-2).⁹

The New York Times and The Washington Post have reported on Chinese researchers' requests to remove the SARS-CoV-2 genetic sequences from the NIH's SRA.¹⁰ According to The Washington Post, "The NIH released a statement [June 23, 2021] saying that a researcher who originally published the genetic sequences asked for them to be removed from the NIH database

⁴ Empower Oversight's July 14th FOIA request is attached as Exhibit 1.

⁵ Zimmer, Carl, *Scientist Finds Early Virus Sequences That Had Been Mysteriously Deleted* (June 23, 2021), available at https://www.nytimes.com/2021/06/23/science/coronavirus-sequences.html; Achenbach, Joel, Guarino, Ben, Abutaleb, Yasmeen, *Seattle Scientist Digs up Deleted Coronavirus Genetic Data, Adding Fuel to the Covid Origin Debate* (June 23, 2021), available at https://www.washingtonpost.com/health/coronavirus-origin-nih-gene-sequence-deletion/2021/06/23/186e87d0-d437-11eb-a53a-3b5450fdca7a">https://www.ashingtonpost.com/health/coronavirus-origin-nih-gene-sequence-deletion/2021/06/23/186e87d0-d437-11eb-a53a-3b5450fdca7a story.html.

⁶ Johns Hopkins University, Mortality Analyses, available at https://coronavirus.jhu.edu/data/mortality (last accessed on February 21, 2022).

⁷ See generally, U.S. Department of State, Fact Sheet: Activity at the Wuhan Institute of Virology, available at <u>https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html</u>.

⁸ U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, available at <u>https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html</u>.

⁹ U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, available at <u>https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html</u>.

¹⁰ Zimmer, Carl, Scientist Finds Early Virus Sequences That Had Been Mysteriously Deleted (June 23, 2021), available at https://www.nytimes.com/2021/06/23/science/coronavirus-sequences.html; Achenbach, Joel, Guarino, Ben, Abutaleb, Yasmeen, Seattle Scientist Digs up Deleted Coronavirus Genetic Data, Adding Fuel to the Covid Origin Debate (June 23, 2021), available at https://www.washingtonpost.com/health/coronavirus-origin-nih-gene-sequence-deletion/2021/06/23/186e87d0-d437-11eb-a53a-3b5450fdca7a_story.html.

so that they could be included in a different database."¹¹ In a statement to *The Washington Post*, the NIH said:

These SARS-CoV-2 sequences were submitted for posting in SRA in March 2020 and subsequently requested to be withdrawn by the submitting investigator in June 2020. The requestor indicated the sequence information had been updated, was being submitted to another database, and wanted the data removed from SRA to avoid version control issues.¹²

And, according to *The New York Times*:

"These SARS-CoV-2 sequences were submitted for posting in SRA in March 2020 and subsequently requested to be withdrawn by the submitting investigator in June 2020," said Renate Myles, a spokeswoman for the National Institutes of Health. She said that the investigator, whom she did not name, told the archive managers that the sequences were being updated and would be added to a different database.¹³

Empower Oversight has no commercial interest in the records sought by its FOIA request, instead it seeks the requested records to contribute significantly to the public's understanding of understanding how the NIH is addressing the SARS-CoV-2 pandemic. Part of NIH's responsibility in that regard necessarily includes furthering efforts to determine the origin of the virus and prevent future pandemics. The potential usefulness of the SARS-CoV-2 genetics sequences that NIH removed from the SRA has ignited an extraordinary interest among the public in research integrity generally and in the NIH's rationale for its removal of the SARS-CoV-2 genetics and operations is at stake, and thus it is Empower Oversight's intention to enlighten the public about these issues.

As November 17, 2021, Empower Oversight had not received any correspondence whatsoever from the NIH concerning its FOIA request, and thus it filed against the NIH a Complaint for Declaratory and Injunctive Relief—Civil Case Number 1:21-cv-01275—in the United States Court for the Eastern District of Virginia. Empower Oversight's complaint seeks, among other things, declarations that the NIH failed to file a timely determination and promptly provide responsive records, an order requiring the NIH to perform a reasonable search and disclose all responsive, non-exempt records, and an award of costs and attorney's fees.

¹¹ Achenbach, Joel, Guarino, Ben, Abutaleb, Yasmeen, *Seattle Scientist Digs up Deleted Coronavirus Genetic Data, Adding Fuel to the Covid Origin Debate* (June 23, 2021), available at <u>https://www.washingtonpost.com/health/coronavirus-origin-nih-gene-sequence-deletion/2021/06/23/186e87d0-d437-11eb-a53a-3b5450fdca7a_story.html</u>.

¹² Achenbach, Joel, Guarino, Ben, Abutaleb, Yasmeen, *Seattle Scientist Digs up Deleted Coronavirus Genetic Data, Adding Fuel to the Covid Origin Debate* (June 23, 2021), available at <u>https://www.washingtonpost.com/health/coronavirus-origin-nih-gene-sequence-deletion/2021/06/23/186e87d0-d437-11eb-a53a-3b5450fdca7a_story.html</u>.

¹³ Zimmer, Carl, Scientist Finds Early Virus Sequences That Had Been Mysteriously Deleted (June 23, 2021), available at https://www.nytimes.com/2021/06/23/science/coronavirus-sequences.html. 601 KING STREET, SUITE 200 | ALEXANDRIA, VA 22314-3151

2. NIH's February 7, 2022, Response to Empower Oversight's FOIA Request

By letter dated February 7, 2022, the NIH responded to Empower Oversight's July 14th FOIA request.¹⁴ In its letter, the NIH designated the request as FOIA Request Number 56712, and produced 238 pages of records, many of which have been redated pursuant to FOIA Exemptions b(5) and b(6). With respect to FOIA Exemption b(5), the NIH explained that its redactions are limited to the deliberative process privilege:

Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making.

ANALYSIS

As discussed in detail below, the 238 pages of records that the NIH produced in response to FOIA Request Number 56712 include evidence indicating that the NIH's FOIA staff made significant errors when searching for responsive records and when reviewing responsive records for FOIA exemptions.

1. <u>The NIH's Search for Responsive Records Was Not Reasonably Calculated to Locate All</u> <u>Records Responsive to Empower Oversight's FOIA Request</u>

The legal standard governing the search for records responsive to FOIA requests requires an agency to conduct a search that is "reasonably calculated to uncover all relevant documents."¹⁵ Such calculation involves both an understanding of the nature and scope of the FOIA request and knowledge of where information may be stored within an agency. In the former regard, courts have found searches to be sufficient when they are based on a reasonable interpretation of the scope of the subject matter of the request.¹⁶

Regarding the issue of knowledge of the contents of an agency's records storage platforms, an agency must show that it conducted a good faith, reasonable search of all platforms likely to possess the requested records.¹⁷ Hence, the reasonableness of an agency's search can often depend on whether the agency properly determined where responsive records were likely to be found—and searched those locations,¹⁸ or whether the agency improperly limited its search to certain platforms.¹⁹

¹⁴ The NIH's February 7, 2021, response to Empower Oversight's July 14th FOIA request is attached as Exhibit 2.

¹⁵ Weisberg v. DOJ, 705 F.2d 1344, 1351 (D.C. Cir. 1983).

¹⁶ Larson v. Dep't of State, 565 F.3d 857, 869 (D.C. Cir. 2009) (affirming the adequacy of a search based on the agency's reasonable determination regarding records being requested).

¹⁷ See, Marino v. DOJ, 993 F. Supp. 2d 1, 9 (D.D.C. 2013) (internal citation omitted).

¹⁸ See, <u>Karantsalis v. DOJ</u>, 635 F.3d 497, 500-501 (11th Cir. 2011) (affirming the district court's determination that the agency searched for records in the system most likely to store responsive records and described how it retrieved records from the system); <u>Lechliter v. Rumsfeld</u>, 182 F. App'x 113, 115-16 (3d Cir. 2006) (concluding that the agency fulfilled its duty to conduct a reasonable search when it searched two offices that it determined would be the only ones likely to possess responsive documents) (*citing Oglesby v. Dep't of the Army*, 920 F.2d 57, 68 (D.C. Cir. 1990).

¹⁹ See, Morley v. CIA, 508 F.3d 1108, 1119-20 (D.C. Cir. 2007) (holding that because the agency retained copies of the records transferred to NARA and concedes that some transferred records are likely to be responsive, it was obligated to search those records in response to the FOIA 601 KING STREET, SUITE 200 | ALEXANDRIA, VA 22314-3151 Page 5 of 20

Courts tend to afford agencies a fair amount of leeway when determining the locations to search for responsive records, on the grounds that an agency generally "is not obliged to look beyond the four corners of [a FOIA] request for leads to the location of responsive" records.²⁰ On the other hand, an agency "cannot in good faith ignore . . . a lead that is both clear and certain."²¹ For example, an agency cannot ignore a responsive document that "clearly indicates the existence of [other] relevant documents."²²

The NIH produced two documents that clearly indicate the existence of other records that it did not produce. In that regard, the NIH produced an August 11, 2021, email from <u>gb-admin@ncbi.nlm.nih.gov</u> to Dr. Jesse Bloom, which has the Subject "GenBank Submissions grp 8164050," and states:

Dear Dr. Bloom,

Thank you for your reply:

I assembled the consensus sequences from a dataset that was generated by Wuhan University, but then deleted from the SRA. So I did not generate the data myself, but wanted to somehow put it in a public sequence database. Is this allowed? https://www.biorxiv.org/content/l0.l101/2021.06.l8.449051v2

GenBank accepts data directly determined by the submitter per our submission guidelines outlined at https://www.ncbi.nlm.nih.gov/genbank/submit types/. In some cases, sequence data not directly obtained by the submitter may be acceptable for the Third Party Annotation database (https://www.insdc.org/documents/tpasubmission-guidelines). However, the primary read data must be present in an INSDC database.

Unfortunately, we are unable to accept your submission since it does not meet the criteria for either GenBank or TPA.

The GenBank Submissions Staff

request); Jefferson v. DOJ, 168 F. App'x 448, 450 (D.C. Cir. 2005) (reversing the district court's finding of a reasonable search when the agency offered no plausible justification for searching only its investigative database and the agency essentially acknowledged that responsive files might exist in a separate database); Oglesby v. Dep't of the Army, 920 F.2d 57, 68 (D.C. Cir. 1990) (holding that the agency may not limit its search to one record system if others are likely to contain responsive records).

²⁰ Kowalczyk v. DOJ, 73 F.3d 386, 389 (D.C. Cir. 1996).

²¹ Kowalczyk, 73 F.3d at 389.

²² <u>Center for National Security Studies v. DOJ</u>, 215 F. Supp. 2d 94, 110 (D.D.C. 2002) (holding that discovery of a document that "clearly indicates the existence of [other] relevant documents" creates an "obligation" for agency to further search for those additional documents), *aff'd in part, rev'd in part & remanded on other grounds*, 331 F.3d 918 (D.C. Cir. 2003); <u>Tarullo v. DOD</u>, 170 F. Supp. 2d 271, 275 (D. Conn. 2001) (declaring agency's search inadequate because "[w]hile hypothetical assertions as to the existence of unproduced responsive documents are insufficient to create a dispute of material fact as to the reasonableness of the search, plaintiff here has [himself provided copy of agency record] which appears to be responsive to the request"); <u>Kronberg v. DOJ</u>, 875 F. Supp. 861, 870 – 871 (D.D.C. 1995) (holding that search was inadequate when agency did not find records required to be maintained and plaintiff produced documents obtained by other FOIA requesters demonstrating that agency possessed files which may contain records sought).

Bethesda, Maryland USA²³

The August 11th email from <u>gb-admin@ncbi.nlm.nih.gov</u> responds to correspondence from Dr. Bloom, which it to characterize as a "reply" to earlier correspondence. However, Dr. Bloom's correspondence and the correspondence that he allegedly replied to are not included among the 238 pages produced by NIH.

Similarly, a July 26, 2021, email from Diane Tuncer to Steve Sherry and Kim Pruitt, which has the Subject "FW: FYI – News Report from China's Xinhua News Agency," states:

Hi Steve and Kim,

We shared this news article with NIH OCPL too, and they [NIH OCPL] responded with the following information (see below). I'm also attaching the last set of QA (which we already sent to you last week).

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]²⁴

The July 26th email forwards to Drs. Sherry and Pruitt a "last set of" questions and answers about Wuhan University dataset that was excluded from public access,²⁵ which Ms. Tuncer asserts had been forwarded to Drs. Sherry and Pruitt during the week of July 19, 2021 (*i.e.*, "last week"). However, the earlier email to Drs. Sherry and Pruitt, which would have been equally responsive to Empower Oversight's FOIA request, was not produced among the 238 pages provided by the NIH. Neither was a separate email referring the Xinhua news article that Ms. Tuncer asserts that "we" sent to the NIH's OCPL.

This evidence that the NIH failed to conduct a search that was reasonably calculated to lead to the discovery of all responsive records does not inspire confidence that the NIH has satisfied its search responsibilities under the FOIA. Hence, Empower Oversight respectfully requests that the NIH, subject to DOJ's monitoring, review the work of its FOIA staff, ascertain the nature and scope of their search plan, determine whether such plan was appropriate and followed,²⁶ correct any errors that are discovered, and apprise Empower Oversight of its findings.

²³ NIH FOIA Request 56712_Redacted, p. 92.

²⁴ NIH FOIA Request 56712_Redacted, p. 93.

²⁵ See, e.g., NIH FOIA Request 56712_Redacted, pp. 96 – 97.

²⁶ Additionally, Federal agencies shoulder the burden of demonstrating that their searches are reasonable, and they typically do this by describing their efforts in affidavits that they file in support of motions for summary judgment. *See, e.g., Ethyl Corp. v. U.S. Environmental* <u>Protection Agency</u>, 25 F.3d 1241 (4th Cir. 1994); <u>Cochran v. Dep't of Homeland Security</u>, 2019 WL 1433014 (D. Md. March 28, 20199). However, an agency may not rely upon vague or conclusory affidavits to show that it has conducted a reasonable search. *See, Cochran*, 2019 WL 1433014, p. *5 – *6 (criticizing a conclusory EBI affidavit). Rather, a satisfactory "affidavit must be reasonably detailed, 'setting forth the search terms and the type of search performed and averring that all files likely to contain responsive materials (if such records exist) were searched' so as to give the requesting party an opportunity to challenge the adequacy of the search." <u>Ethyl Corp.</u>, 25 F.3d 1246 – 1247 (*quoting Oglesby v.* <u>U.S. Dep't of the Army</u>, 920 F.2d 57, 68 (D.C. Cir. 1990)). Accordingly, Empower Oversight requests that the NIH generate and share with Empower Oversight affidavits fully describing the search efforts of the NIH's FOIA staff.

2. <u>The NIH Asserted FOIA Exemption b(5) as Justification for Redacting Responsive Records</u> <u>that Are Not Both Pre-decisional and Deliberative</u>

Subsection b(5) of the FOIA provides that the FOIA "does not apply to matters that are":

inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.²⁷

Courts have construed FOIA Exemption b(5) to "exempt those documents, and only those documents, that are normally privileged in the civil discovery context."²⁸ Although the United States Circuit Court of Appeals for the District of Columbia Circuit ("Circuit Court") has held that "all civil discovery rules" are incorporated into FOIA Exemption b(5),²⁹ the NIH's February 7th response to NIH FOIA Case Number 56712 appears to limit the NIH's reliance on the exemption to the deliberative process privilege (*i.e.*, the NIH states, "Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations").

The purpose of the deliberative process privilege is to "prevent injury to the quality of agency decisions."³⁰ In this setting, the Circuit Court has explained that "quality" encompasses encouraging frank discussions during policy making, preventing advance disclosure of decisions, and protecting against public confusion that may result from disclosure of reasons or rationales that were not in fact the grounds for agency decisions.³¹

To claim the deliberative process privilege with respect to a record, the Circuit Court has held that an agency must show³² that the record is "pre-decisional" (*i.e.*, "antecedent to the adoption of agency policy")³³ and "deliberative" (*i.e.*, "a direct part of the deliberative process in that it makes recommendations and expresses opinions on legal or policy matters").³⁴

Unfortunately, it appears that the NIH, while purporting to follow FOIA Exemption b(5), has redacted responsive records that are **<u>not</u>** both pre-decisional and deliberative.

³² Coastal States Gas Corp., 617 F.2d at 866.

^{27 5} U.S.C. § 552(b)(5).

²⁸ NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 149 (1975); see also, Martin v. Office of Special Counsel, 819 F.2d 1181, 1184 (D.C. Cir. 1987).

²⁹ See, Martin, 819 F.2d at 1185.

³⁰ Sears, 421 U.S. at 151.

³¹ See, <u>Russell v. Dep't of the Air Force</u>, 682 F.2d 1045, 1048 (D.C. Cir. 1982); <u>Coastal States Gas Corp. v. DOE</u>, 617 F.2d 854, 866 (D.C. Cir. 1980); <u>Jordan v. DOJ</u>, 591 F.2d 753, 772 – 773 (D.C. Cir. 1978).

³³ See, Ancient Coin Collectors Guild v. U.S. Dep't of State, 641 F.3d 504, 513 (D.C. Cir. 2011).

³⁴ See, <u>Vaughn v. Rosen</u>, 523 F.2d 1136, 1143 – 1144 (D.C. Cir. 1975).

A. The NIH Redacted Records that Are Not Pre-decisional

The Circuit Court has held that a document is "pre-decisional," if it is "generated before the adoption of an agency policy."³⁵ In determining whether a document is antecedent to the generation of agency policy, courts have found that an agency does not necessarily have to point to a specific agency final decision,³⁶ but instead it must establish "what deliberative process is involved, and the role played by the documents at issue in the course of that process."³⁷

On this point, the Supreme Court has been clear:

Our emphasis on the need to protect pre-decisional documents does not mean that the existence of the privilege turns on the ability of an agency to identify a specific decision in connection with which a memorandum is prepared. Agencies are, and properly should be, engaged in a continuing process of examining their policies; this process will generate memoranda containing recommendations which do not ripen into agency decisions; and the lower courts should be wary of interfering with this process.³⁸

Thus, a document must be generated as part of such a continuing process of agency decisionmaking for a court to find that FOIA Exemption b(5) is applicable.³⁹

Communication with Dr. Bloom About a Request by a Wuhan University Researcher to Exclude a Genome Dataset from the SRA

The NIH produced a record that its FOIA staff heavily redacted, purportedly pursuant to FOIA Exemption b(5), that clearly was not part of the NIH's decision-making process. In that regard, on Friday, June 18, 2020, at 7:00 pm, Dr. Jesse Bloom emailed Francis Collins, Steve Sherry, and Anthony Fauci to alert them that he had "identified a data set of early Wuhan SARS-CoV-2 sequences that has been deleted from the NIH's" SRA, to forward a copy of his pre-print analysis of his recovery of the deleted data files from the Google Cloud, and to recommend that the NIH commence a comprehensive examination of the SRA to search for other SARS-CoV-2 genomes that may have been deleted.⁴⁰

The next morning, June 19, 2021, at 7:34 am, Steve Sherry sent Francis Collins, Jesse Bloom, Anthony Fauci, and Patti Brennan an email, which has the Subject "RE: SARS-CoV-2 Data Deleted from the NIH/NCBI SRA," and stated:

Dear Francis and Jesse,

³⁵ Judicial Watch, Inc. v. FDA, 449 F.3d 141, 151 (D.C. Cir. 2006).

³⁶ Rein v. U.S. Patent & Trademark Office, 553 F.3d 353, 373 (4th Cir. 2009).

³⁷ Coastal States Gas Corp. v. DOE, 617 F.2d 854, 868 (D.C. Cir. 1980).

³⁸ NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 n.18 (1975).

³⁹ See, e.g., <u>New Hampshire Right to Life v. HHS</u>, 778 F.3d 43, 53 – 54 (1st Cir. 2015).

⁴⁰ NIH FOIA Request 56712_Redacted, pp. 176 – 177.

Below is the June 2020 exchange between Wuhan University and SRA submission staff. I have redacted names and the withdrawal request tracking ID for privacy. Please read from the bottom up.

I would note that this request was received and processed according to SRA policy. As Jesse notes in his manuscript, submitters own their SRA records and can withdraw them upon request. SRA does not adjudicate the reason.

More generally, I have requested the SRA team to compile a report of all withdrawn SARS-COV2 data so there is transparency into the status of all SRA SARS-COV2 sequence submissions. I will share the report as soon as it is available.

Kind regards,

Steve

(data withdrawal correspondence) ------

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]⁴¹

Here, the NIH, in response to unsolicited correspondence from an external party (*i.e.*, Dr. Bloom), shares with Dr. Bloom a communication thread that Dr. Sherry characterizes as being a "June 2020 exchange between Wuhan University and SRA submission staff" from which he redacted names and a tracking identification number for "privacy" purposes (and at NIH FOIA Request 56712_Redacted, pages 174 - 176, the NIH FOIA staff redacts the exchange in its entirety).⁴² Thus, according to Dr. Sherry the redacted information is not part of the agency decision-making process: it represented a correspondence exchange between the NIH and Wuhan University concerning public access to SARS-CoV-2 data that Wuhan University had posted on the SRA and later wished to exclude from public access. If there were an agency policy decision involved, then it would have been the decision whether to grant Wuhan University's request, which Dr. Sherry describes as being something that the NIH grants as a matter of course without "adjudicate[ing] the reason" for the request, or to follow Dr. Bloom's recommendation to examine the SRA, which Dr. Sherry advised he had implemented.

⁴¹ NIH FOIA Request 56712_Redacted, pp. 174 – 176.

⁴² The NIH appears to have twice produced Dr. Sherry's June 19th email. *Compare*, NIH FOIA Request 56712_Redacted, pp. 174 – 176, and NIH FOIA Request 56712_Redacted, pp. 229 – 230. As shown above, the version produced at pages 174 – 176 is fully redacted, purportedly pursuant to FOIA Exemption b(5), whereas the version produced at pages 229 – 230 includes the exchange as described by Dr. Sherry in his email. The NIH's FOIA staff producing the same record with redactions at pages 174 – 176 and without redactions at pages 229 – 230 further undermines the credibility of their exemption claim.

Moreover, much of the text redacted at pages 174 – 176, assuming that it is the same text that is produced without redaction at pages 229 – 230, is replete with factual information, *compare*, NIH FOIA Request 56712_Redacted, pp. 174 – 176, and NIH FOIA Request 56712_Redacted, pp. 229 – 230, which, as described in the next section, is not protected by FOIA Exemption b(5).

Internal Dissemination of Coverage of Dr. Bloom's Findings by the Official Press Agency of the Republic of China

Similarly, the NIH produced a July 26, 2021, email from Diane Tuncer to Steve Sherry and Kim Pruitt, which has the Subject FW: FYI – News Report from China's Xinhua News Agency," that purports to forward "information" from the NIH's Office of Communications and Public Liaison ("OCPL"). Further, given the context of the email, the forwarded "information" would appear to pertain to OCPL's analysis of an article published in Xinhua,⁴³ as opposed to an NIH policy under consideration.⁴⁴ Ms. Tuncer's July 26th email states:

Hi Steve and Kim,

We shared this news article with NIH OCPL too, and they [NIH OCPL] responded with the following information (see below). I'm also attaching the last set of QA (which we already sent to you last week).

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]⁴⁵

B. The NIH Redacted Records that Are Not Deliberative

To be "deliberative," a record must reflect[] the give-and-take of the consultative process," either by assessing the merits of a particular viewpoint, or by articulating the process used by the agency to formulate policy.⁴⁶

Factual information, on the other hand, is not covered by the deliberative process privilege because the release of factual information does not expose the deliberations or opinions of agency personnel.⁴⁷ Accordingly, factual information is typically available in civil discovery and its release is not considered to have a chilling effect on agency deliberations.⁴⁸

Empower Oversight cannot see behind the NIH's redactions, but other records produced by the NIH raise serious questions regarding whether segregable factual information⁴⁹ is included within numerous large text block redactions that the NIH's FOIA staff has made.

⁴³ Xinhua is an official news service run by the Chinese state. *See*, Markay, Lachlan, *China Increases Spending 500% to Influence America* (May 11, 2021), available at https://www.axios.com/china-foreign-influence-spending-317a9be4-8ead-4abf-8ac4-3f27974d7a9d.html. As such, its United States branch is registered as a foreign agent under the Foreign Agents Registration Act, 22 U.S.C. § 611 *et seq. Id*.

⁴⁴ Additionally, unless the information that Ms. Tuncer forwarded from OCPL excludes, for example, addressees, dates, and subject lines, it clearly includes non-deliberative, factual information such as that discussed in the next section.

⁴⁵ NIH FOIA Request 56712_Redacted, p. 93.

⁴⁶ Coastal States Gas Corp., 617 F.2d at 867.

⁴⁷ <u>Coastal States Gas Corp.</u>, 617 F.2d at 867; *see also*, <u>McGrady v. Mabus</u>, 635 F. Supp. 2d 6, 18 – 21 (D.D.C. 2009) (distinguishing between draft letters and memoranda that may be deliberative and data used during a decision-making process, *e.g.*, key personnel data and evaluation summaries used in promotion decisions, which contain only factual material and are not deliberative).

⁴⁸ See, <u>EPA v. Mink</u>, 410 U.S. 73, 87 – 88 (1973); see also, <u>Montrose Chem. Corp. v. Train</u>, 491 F.2d 63, 66 (D.C. Cir. 1974) (holding that release of factual material would not be "injurious" to decision making process).

 ⁴⁹ "[W]ith regard to any document an agency believes falls under a FOIA exemption, the agency is required to "undertake a 'segregability analysis,' in which it separates the exempt from the non-exempt portions of the document, and produces the relevant non-exempt
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Planned Response to Media Inquiries Concerning Dr. Bloom's Reference to the Exclusion of Information from Public Access on the SRA

The NIH produced a thread of emails that were designed to formulate an official response to an expected surfeit of media inquiries and—seemingly consistent with the policy underlying FOIA Exemption b(5)—emails that were created before the adoption of the official response include text block redactions. In several cases large ones. However, comparison of the pre-adoption emails with the official response that was ultimately adopted begs the question whether segregable factual information is included among the NIH's redactions. For example, a June 21, 2021, 2:25 pm, email from Renate Myles to Diane Tuncer and Jody Nurik, which has the Subject "FLAGGING: SARS-CoV-2 dated deleted from the NIH/NCBI SRA," states:

Hi all:

The attached paper was submitted to BioRx for preprint. The researcher is focusing on early genome sequence data on SARS-CoV-2 that the submitter requested be deleted. Unfortunately, the author of the paper is assigning motive and suggesting that the purpose of deletion was to obscure its existence. Below are reactive statement and QA in case we get media interest. Please let me know ASAP if NLM has any concerns with this language.

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

Was there any motive for the investigator to remove the data? [Text block redacted purportedly pursuant to FOIA Exemption b(5).]

Are investigators allowed to request that data be deleted from SRA? [Text block redacted purportedly pursuant to FOIA Exemption b(5).]⁵⁰

A June 21, 2021, 6:22 pm, email from Renate Myles to Diane Tuncer and Jody Nurik, which has the Subject "RE: FLAGGING: SARS-CoV-2 dated deleted from the NIH/NCBI SRA," states:

Hi Diane:

Spoke with Patti and below is what we agreed on. So far, the paper still has not posted. We're keeping an eye out for it.

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

Was there any motive for the investigator to remove the data? [Text block redacted purportedly pursuant to FOIA Exemption b(5).]

Are investigators allowed to request that data be deleted from SRA?

information." <u>People for the American Way Foundation v. National Park Service</u>, 503 F. Supp. 2d 284, 306 (D.D.C. 2007) (*quoting Edmonds* Institute v. U.S., 383 F. Supp.2d 105, 108 (D.D.C. 2005)).

⁵⁰ NIH FOIA Request 56712_Redacted, pp. 21 – 22.

[Text block redacted purportedly pursuant to FOIA Exemption b(5).]⁵¹

However, a June 22, 2021, email from Renate Myles to Jody Nurik and Diane Tuncer, which has the Subject "RE: FLAGGING: SARS-CoV-2 dated deleted from the NIH/NCBI SRA," states:

Thanks, Jody. We'll need lots of eyes. Also, I made as light tweak to the response. We'll handle it here.

NIH is aware of Dr. Bloom's preprint submission. Staff at the National Library of Medicine, which hosts the Sequence Read Archive (SRA), have reviewed the submitting investigator's request to withdraw the data. These SARS-CoV-2 sequences were submitted for posting in SRA in March 2020 and subsequently requested to be withdrawn by the submitting investigator in June 2020. The requestor indicated the sequence information had been updated, was being submitted to another database, and wanted the data removed from SRA to avoid version control issues. The submitting investigator published relevant information about these sequences by preprint in March, 2020 and in a journal in June, 2020. Submitting investigators hold the rights to their data and can request withdrawal of the data.

Was there any motive for the investigator to remove the data?

NIH can't speculate on motive beyond the investigator's stated intentions.

Are investigators allowed to request that data be deleted from SRA?

Submitting investigators hold rights to their data and can request withdrawal of the data[.]⁵²

Thus, unless the text redacted from Ms. Myles' two June 21st emails differ dramatically from the text of her June 22nd email, which she characterizes as including only a "light tweak," the NIH's FOIA staff have redacted a surplus of factual information from the June 21st emails. Indeed, Ms. Myles' June 22nd email is entirely factual in nature; there is no policy discussion reflected therein. She advises that:

- NIH is aware of Dr. Bloom's preprint article;
- Staff at the NLM, which hosts the SRA, have reviewed the Wuhan University researcher's request to withdraw SARS-CoV-2 genetic data from the SAR;
- The data in question was submitted for posting on the SRA in March 2020, and the withdraw request was submitted in June 2020;

⁵¹ NIH FOIA Request 56712_Redacted, p. 20.

⁵² NIH FOIA Request 56712_Redacted, p. 19. In July of 2021, NIH internally disseminated a more detailed question/answer sheet for responding to media inquiries concerning the Wuhan University dataset that was excluded from public access on the SRA. *See*, NIH FOIA Request 56712 Redacted, p. 96 – 97.

- The Wuhan University requester had indicated that the data in question had been updated, was being submitted to another database, and that the removal from the SRA was intended to avoid version control issues;
- Submitting researchers hold the rights to their data and can request the withdrawal thereof; and
- The NIH can't speculate on motive beyond the requester's stated intentions.

Response to Inquiry by Dr. Bloom Related to an Assembly of "Consensus Sequences" of a Dataset Generated by Wuhan University and Later Excluded from Public Access on the SRA

Similarly, the NIH produced a thread of emails that were designed to respond to an offer from Dr. Bloom, who had advised that he had assembled "consensus sequences" of the genetic data that the Wuhan University researcher(s) had requested that the NIH remove from public access on the SRA, and sought permission to upload such sequences to the GenBank.⁵³ Again, unless the pre-response emails differ dramatically from the text of the August 11, 2021, response to Dr. Bloom, the NIH FOIA staff redacted a significant amount of factual information that is not exempt from disclosure under FOIA Exemption b(5).

In that regard, an August 5, 2021, 5:35 pm, email from Ilene Mizrachi to Kim Pruitt and Steve Sherry, which has the Subject "Genome Assemblies from Jesse Bloom," states:

Hi,

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

Ilene⁵⁴

Likewise, an August 5, 2021, 5:49 pm, email from Kim Pruitt to Steve Sherry, Ilene Mizrachi, Patti Brennan, and Teresa Zayas Caban, which has the Subject "RE: Genome Assemblies from Jesse Bloom," states:

Was just about to send this reply —

⁵³ GenBank is the NIH's annotated collection of all publicly available DNA sequences. *See*, National Center for Biotechnology Information ("NCBI"), *GenBank Overview* (Last Updated April 26, 2021), available at https://www.ncbi.nlm.nih.gov/genbank/. It is part of the International Nucleotide Sequence Database Collaboration ("INSDC") with the DNA DataBank of Japan and the European Nucleotide Archive. *Id*. The DNA sequences compiled in GenBank are submitted by the researcher that sequenced the DNA in question. *See*, NCBI, *What Is a Third Party Annotation (TPA) Sequence?* (Last Updated October 15, 2020), available at https://www.ncbi.nlm.nih.gov/genbank/tpa/.

On the other hand, the SRA is a data base of raw "sequencing data from the next generation of sequencing platforms including Roche 454 GS System[®], Life Technologies AB SOLiD Systems[®], Helicos Biosciences Heliscope[®], Complete Genomics[®], and Pacific Biosciences SMRT[®]." *See*, NCBI, DNA & RNA: Databases (Undated), available at https://www.ncbi.nlm.nih.gov/guide/dna-rna/. And, the Third Party Annotation Sequence is an NIH "database designed to capture experimental or inferential results that support submitter-provided annotation for, or assembly of, sequence data that the submitter did not" sequence but rather "derived from GenBank primary data." *See*, NCBI, *What Is a Third Party Annotation (TPA) Sequence*? (Last Updated October 15, 2020), available at https://www.ncbi.nlm.nih.gov/genbank/tpa/.

⁵⁴ NIH FOIA Request 56712_Redacted, pp. 90 – 91.

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

Options:

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

Kim⁵⁵

An August 6, 2021, 12:28 pm, email from Ilene Mizrachi to Kim Pruitt, Steve Sherry, Patti Brennan, and Teresa Zayas Caban, which has the Subject "RE: Genome Assemblies from Jesse Bloom," states:

This is the reply that we would like to send to Bloom. Is it ok?

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]⁵⁶

An August 9, 2021, 7:15 am, email from Teresa Zayas Caban to Steve Sherry, Ilene Mizrachi, Kim Pruitt, and Patti Brennan, which has the Subject "RE: Genome Assemblies from Jesse Bloom," states:

Good morning all,

Am conferring with OGC on this but was wondering [text block redacted purportedly pursuant to FOIA Exemption b(5)].

-Teresa⁵⁷

An August 9, 2021, 12:12 pm, email from Linda Yankie to Teresa Zayas Caban, Steve Sherry, Ilene Mizrachi, Kim Pruitt, and Pattie Brennan, which has the Subject "RE: Genome Assemblies from Jesse Bloom," states:

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]⁵⁸

And, an August 9, 2021, 7:21 pm, email from Teresa Zayas Caban to Linda Yankie, Steve Sherry, Ilene Mizrachi, Kim Pruitt, and Patti Brennan, which has the Subject "RE: Genome Assemblies from Jesse Bloom," states:

Pre-Decisional – Deliberative – Do Not Disclose

I conferred with OGC [text block redacted purportedly pursuant to FOIA Exemption b(5)].

⁵⁵ NIH FOIA Request 56712_Redacted, pp. 89 – 90.

⁵⁶ NIH FOIA Request 56712_Redacted, pp. 87 – 88.

⁵⁷ NIH FOIA Request 56712_Redacted, p. 87.

⁵⁸ NIH FOIA Request 56712_Redacted, p. 86.

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

[Large text block redacted purportedly pursuant to FOIA Exemption b(5).]

The GenBank Submissions Staff Bethesda, Maryland USA⁵⁹

Whereas, the August 11, 2021, email from <u>gb-admin@ncbi.nlm.nih.gov</u> to Dr. Jesse Bloom, which has the Subject "GenBank Submissions grp 8164050," states:

Dear Dr. Bloom,

Thank you for your reply:

I assembled the consensus sequences from a dataset that was generated by Wuhan University, but then deleted from the SRA. So I did not generate the data myself, but wanted to somehow put it in a public sequence database. Is this allowed? https://www.biorxiv.org/content/l0.l101/2021.06.l8.449051v2

GenBank accepts data directly determined by the submitter per our submission guidelines outlined at https://www.ncbi.nlm.nih.gov/genbank/submit types/. In some cases, sequence data not directly obtained by the submitter may be acceptable for the Third Party Annotation database (https://www.insdc.org/documents/tpa-submission-guidelines). However, the primary read data must be present in an INSDC database.

Unfortunately, we are unable to accept your submission since it does not meet the criteria for either GenBank or TPA.

The GenBank Submissions Staff Bethesda, Maryland USA⁶⁰

Thus, after quoting Dr. Bloom's earlier correspondence, a fact, the NIH adds the following facts:

- Its GenBank only accepts data from researchers that have directly prepared the sequences, according to its guidelines published at https://www.ncbi.nlm.nih.gov/genbank/submit types/;
- Experimental and inferential results from genetic sequences may be accepted by the Third Party Annotation ("TPA") database, <u>https://www.insdc.org/documents/tpa-submission-guidelines</u>, if the

⁵⁹ NIH FOIA Request 56712_Redacted, pp. 85 – 86.

⁶⁰ NIH FOIA Request 56712_Redacted, p. 92.

underlying genetic sequence is posted in an International Nucleotide Sequence Database Collaboration ("INSDC") database, such as GenBank; but

• The data offered by Dr. Bloom does not comply with the requirements of GenBank or the TPA.

This evidence that the NIH inappropriately used FOIA Exemption b(5)-i.e., that while purporting to follow FOIA Exemption b(5), the NIH redacted responsive records that are **not** both pre-decisional and deliberative—does not inspire confidence that the NIH has satisfied its review responsibilities under the FOIA. Hence, Empower Oversight respectfully requests that the NIH, subject to DOJ's monitoring, analyze all of its FOIA staff's FOIA Exemption b(5) claims in response to FOIA Case Number 56712—not just the items described above—to ensure that their claims are consistent with the accepted legal parameters of the exemption, correct any errors that are discovered, and apprise Empower Oversight of its findings.

3. <u>The NIH Asserted FOIA Exemption b(6) as Justification for Redacting Responsive Records</u> <u>that Do Not Invoke Substantial Privacy Interests</u>

Subsection b(6) of the FOIA provides that the FOIA "does not apply to matters that are ... personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."⁶¹ Courts have found that the plain language of FOIA Exemption b(6) requires agencies to engage in a four-step analysis of records that are potentially responsive to a FOIA request; agencies must:

- 1. Determine whether a record at issue constitutes a personnel, medical, or "similar" file;
- 2. Determine whether there is a substantial privacy interest invoked by information in such records;
- 3. Evaluate the requester's asserted FOIA public interest in disclosure of the records that include information that invoke a substantial privacy interest; and
- 4. Balance competing interests to determine whether disclosure of the records "would constitute a clearly unwarranted invasion of personal privacy," if there is a FOIA public interest in disclosure of records that include information that invokes a substantial privacy interest.⁶²

Each step of the FOIA Exemption b(6) analysis is dependent upon the prior step being satisfied; hence, for example, if the information in question does not satisfy the threshold requirement (*i.e.*, a personnel, medical, or similar file), it is unnecessary to evaluate the existence and significance of privacy interests because the exemption is inapplicable.⁶³

^{61 5} U.S.C. § 552(b)(6).

⁶² See, <u>Multi Ag Media LLC v. USDA</u>, 515 F.3d 1224, 1229 (D.C. Cir. 2008); <u>NARA v. Favish</u>, 541 U.S. 157, 172 (2004); <u>Wash. Post Co. v. HHS</u>, 690 F.2d 252, 261 (D.C. Cir. 1982).

^{63 &}lt;u>Schonberger v. NTSB</u>, 508 F. Supp. 941, 942 (D.D.C. 1981).

Further, courts generally have declined to find that the identities of citizens who have petitioned the government to take an action to be information that raises substantial privacy interests protected under FOIA Exemption b(6).⁶⁷ They also have declined to find the identities of government officials to represent substantial privacy interests protected by the exemption.⁶⁸

In contrast to this precedent, the NIH—purportedly in reliance on FOIA Exemption b(6)—has redacted the name(s) of one or more Wuhan University⁶⁹ researcher(s) who petitioned it to remove genome sequence data that he/she/they had submitted to the SRA for posting. In that regard, pages 23 – 24, 35, 65, 70 – 72, 75 – 83, 103, 115, 145, and 150 – 163 of the 238 pages that the NIH produced in response to FOIA Case Number 56712 include emails and correspondence between the NIH staff and one or more external contact(s) whose name(s) and business affiliation(s)⁷⁰ is(are) redacted—allegedly pursuant to FOIA Exemption b(6). The emails and correspondence relate to:

• The NIH's March 2020 acknowledgment of receipt of genome sequence data—for posting on the SRA—from the external contact(s);⁷¹

⁶⁷ People for the American Way Foundation, 503 F. Supp. 2d at 306 (determining that the mere identity of individuals who voluntarily submitted comments regarding a proposal to change a video displayed for guests at the Lincoln Memorial does not raise the kind of privacy concerns protected by FOIA Exemption b(6)) (quoting Lardner v. U.S. Department of Justice, 2005 WL 758267, at * 18 (D.D.C. 2005)); see also, Landmark Legal Found. v. IRS, 87 F. Supp. 2d 21, 27 – 28 (D.D.C. 2000); Alliance for Wild Rockies v. Department of the Interior, 53 F. Supp.2d 32, 34 (D.D.C. 1999).

⁶⁸ See, e.g., Aguirre v. SEC, 551 F. Supp. 2d 33, 54 (D.D.C. 2008) ("Correspondence does not become personal solely because it identifies government employees").

⁶⁹ Wuhan University describes itself as "a... key university directly under the administration of the Ministry of Education. It is also one of the "211 Project' and '985 Project' universities with full support in the construction and development from the central and local government of China." *See*, Wuhan University, *About WHU: Overview* (2014), available at <u>https://en.whu.edu.cn/About_WHU1/Overview.htm</u>.

⁷⁰ Although the NIH FOIA staff typically redacted the business affiliations of the external contact(s), *i.e.*, Wuhan University, they neglected to do so with respect to a June 19, 2020, email from Steve Sherry to Francis Collins, Jesse Bloom, Anthony Fauci, and Patti Brennan. *See*, NIH FOIA Request 56712_Redacted, pp. 229 - 230. By his email, he forwarded a thread of three June 2020 emails between a Wuhan University "Submitter" and a "SRA Curator." The submitter's name and the data identification numbers were redacted by Dr. Sherry, but he failed to redact "Wuhan University" in the contact's(s') salutation block. *See*, NIH FOIA Request 56712_Redacted, pp. 230; *compare*, NIH FOIA Request 56712_Redacted, pp. 81 – 82.

⁶⁴ See, <u>Multi Ag Media LLC</u>, 515 F.3d at 1229 (quoting <u>National Association of Retired Federal Employees v. Horner</u>, 879 F.2d 873, 874 (D.C. Cir. 1989)).

⁶⁵ <u>Department of the Air Force v. Rose</u>, 425 U.S. 352, 380 n.19 (1976) ("The legislative history is clear that Exemption 6 was directed at threats to privacy interests more palpable than mere possibilities.")

⁶⁶ National Association of Retired Federal Employees v. Horner, 879 F.2d 873, 878 (D.C. Cir. 1989) (citing <u>Arieff v. U.S. Department of the Navy</u>, 712 F.2d 1462, 1468 (D.C. Cir. 1983)), *see also*, <u>Pinson v. DOJ</u>, 313 F. Supp. 3d 88, 112 (D.D.C. 2018) (finding that "conclusory" and "generalized" allegations of privacy harms are insufficient for protection of records under Exemption 6); <u>Aqualliance v. U.S. Army Corps. of Engineers</u>, 243 F. Supp. 3d 193, 198 (D.D.C. 2017) (finding mailing lists of homeowners who lived in close proximity to a California water project to be too speculative to be protected by FOIA Exemption b(6)).

⁷¹ A March 17, 2020, email from "sra" to "b(6)," with the Subject "SRA submission SUB7147304, 'Nanopore targeted sequencing for SARS-CoV-2 and other respiratory viruses, Mar 13 '20'" is an automatic acknowledgment of "b(6)"'s "recent submission to the SRA database." *See*, NIH FOIA Request 56712_Redacted, p. 70. The title in the subject line of the email corresponds to a pre-print article, *Nanopore Target Sequencing* 601 KING STREET, SUITE 200 | ALEXANDRIA, VA 22314-3151 Page 18 of 20

- The NIH's designation of the March 2020 data as Submission ID 7147304 and BioProject Accession Number PRJNA612766;
- Troubleshooting concerning access to the data on the SRA;
- The NIH's June 2020 acknowledgment of receipt of genome sequence data—for posting on the SRA—from the external contact(s);
- The NIH's designation of the June 2020 data as Submission ID 7554642 and BioProject Accession Number PRJNA637497;
- The external contact's(s') request to "retract" Submission ID 7554642 and BioProject Accession Number PRJNA637497, and the NIH's hesitance to do so;
- The external contact's(s') request, with the Subject "Re: SUB7554642/subs/sra/SUB7554642/overview," to "withdraw" Submission ID 7147304; and
- The NIH's inquiry regarding the scope of the external contact's(s') request, and confirmation that it "had withdrawn everything."

The external contact(s) are—on the basis of Dr. Sherry's June 19th email⁷² and the title of the preprint publication associated with Submission ID 7147304 and BioProject Accession Number PRJNA612766⁷³—affiliated with Wuhan University, and thus in some fashion is(are) employed by the Chinese government. In other words, they are government officials operating in their official capacity. Moreover, the external contact(s) clearly petitioned the NIH to take action with respect to Submission IDs 7147304 and 7554642, and BioProject Accession Numbers PRJNA612766 and PRJNA637497, *i.e.*, to "retract" or "withdraw" them from the SRA. Accordingly, the external contact(s) and business affiliation should not have been redacted the NIH.⁷⁴

Moreover, were the precedent controlling the privacy interests associated with petitions for government action and government employees' official actions not fatal to the NIH FOIA staff's FOIA Exemption b(6) assertions on pages 23 - 24, 35, 65, 70 - 72, 75 - 83, 103, 115, 145, and 150 - 163 of the NIH's production, the question would arise whether there is a substantial privacy interest at stake in the first place. It seems unlikely that there is. The data designated Submission ID 7147304 and BioProject Accession Number PRJNA612766 was submitted to the NIH to facilitate peer review of the methodology underlying a pre-print report

for Accurate and Comprehensive Detection of SARS-CoV-2 and Other Respiratory Viruses (March 2020), that was submitted by 15 authors affiliated with Wuhan University, the Ministry of Education, Wuhan Dgensee Clinical Laboratory Co., Ltd., the Wuhan Institute of Virology, Shanghai Jiao Tong University, and the Wuhan Institute of Biotechnology. See, Hu, Ben, et al, Nanopore Target Sequencing for Accurate and Comprehensive Detection of SARS-CoV-2 and Other Respiratory Viruses (March 2020), available at https://pubmed.ncbi.nlm.nih.gov/32578378/.

⁷² See footnotes 70, above.

⁷³ See footnotes 71, above.

⁷⁴ Indeed, although Dr. Sherry erroneously counseled staff to redact the names of the external contact(s), several NIH staffers questioned his guidance. See NIH FOIA Request 56712_Redacted, pp. 169 – 171. Apparently, to no avail.

entitled Nanopore Target Sequencing for Accurate and Comprehensive Detection of SARS-CoV-2 and Other Respiratory Viruses, which was submitted by 15 authors who freely attached their names thereto. It seems implausible that such authors now would wish to be disassociated with their report or the methodology supporting their research. Additionally, the NIH has publicly stated that the authors of Nanopore Target Sequencing for Accurate and Comprehensive Detection of SARS-CoV-2 and Other Respiratory Viruses: 1) own the genetic data that they submitted to the SRA for posting, and 2) have the complete discretion to "retract" or "withdraw" such data from public access on the SRA. It thus seems equally implausible that the authors assertion of ownership over their data and their exercise of discretion over the use of it would implicate a privacy issue. And, to date, the NIH has not offered any clues concerning what such a privacy interest may look like.

This evidence that the NIH inappropriately used FOIA Exemption b(6) does not inspire confidence that the NIH has satisfied its review responsibilities under the FOIA. Hence, Empower Oversight respectfully requests that the NIH, subject to DOJ's monitoring, analyze all of its FOIA staff's FOIA Exemption b(6) claims in response to FOIA Case Number 56712—not just the items described above—to ensure that their claims are consistent with the accepted legal parameters of the exemption, correct any errors that are discovered, and apprise Empower Oversight of its findings. Moreover, because "[a]n agency [in litigation] must provide affidavits containing 'reasonable specificity of detail rather than merely conclusory statements' to establish a substantial invasion of privacy,"⁷⁵ Empower Oversight requests that the NIH provide affidavits supporting its findings.

Thank you for your time and consideration. Please don't hesitate to contact me with any questions.

Cordially,

/Jason Foster/

Jason Foster Founder & President

⁷⁵ <u>Climate Investigations Center v. DOE</u>, 331 F. Supp. 3d 1, 26 (D.D.C. 2018) (*quoting* <u>Judicial Watch</u>, Inc. v. U.S. Secret Service, 726 F.3d 208, 215 (D.C. Cir. 2013)).

Exhibit 1



Whistleblowers & Research



July 14, 2021

VIA ELECTRONIC TRANSMISSION: NIHFOIA@MAIL.NIH.GOV

National Institutes of Health Building 31 Room 5B35 9000 Rockville Pike Bethesda, MD 20892

RE: RECORDS REGARDING NIH'S SARS-COV-2 (COVID19) DATABASE

Dear FOIA Officer:

Empower Oversight Whistleblowers & Research ("Empower Oversight") is a nonpartisan, nonprofit educational organization dedicated to enhancing independent oversight of government and corporate wrongdoing. We work to help insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities help to hold those authorities accountable to act on such reports.

We respectfully request records be delivered from the National Institutes of Health (NIH) pursuant to this request under the Freedom of Information Act (FOIA), 5 U.S.C. 552 within the next 20 business days. As detailed below, we request access to certain records regarding SARS-CoV-2 sequences submitted for posting to the Sequence Read Archive in March 2020 by Chinese researchers and subsequently requested to be withdrawn by the submitting investigator in June 2020. Sequences of SARS-CoV-2 virus are critical to understanding how this pandemic (which has killed more than 600,000 Americans) started, in order to prevent future pandemics.¹ Furthermore, the State Department has noted that China has not been transparent in its handling of the SARS-CoV-2 origin question and has removed virus sequences from its own online databases that could help uncover how the pandemic started.²

The *New York Times* and the *Washington Post* have reported on requests to remove these sequences and this removal has added fuel to the SARS-CoV-2 origin debate.³

¹ "COVID Mortality Data," Johns Hopkins University (<u>https://coronavirus.jhu.edu/data/mortality</u>).

² "Fact Sheet on Activity at the Wuhan Institute of Virology," U.S. State Dep't (<u>https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html</u>)

³ "Scientist Finds Early Virus Sequences That Had Been Mysteriously Deleted," *New York Times* (Jun 23, 2021); "Seattle scientist digs up deleted coronavirus genetic data, adding fuel to the covid origin debate," *Washington Post* (Jun 23, 2021).

According to the *Washington Post*, "The NIH released a statement Wednesday saying that a researcher who originally published the genetic sequences asked for them to be removed from the NIH database so that they could be included in a different database."⁴ In a statement to the *Washington Post*, the NIH said:

These SARS-CoV-2 sequences were submitted for posting in SRA in March 2020 and subsequently requested to be withdrawn by the submitting investigator in June 2020. The requestor indicated the sequence information had been updated, was being submitted to another database, and wanted the data removed from SRA to avoid version control issues.⁵

And, according to the New York Times:

"These SARS-CoV-2 sequences were submitted for posting in SRA in March 2020 and subsequently requested to be withdrawn by the submitting investigator in June 2020," said Renate Myles, a spokeswoman for the National Institutes of Health. She said that the investigator, whom she did not name, told the archive managers that the sequences were being updated and would be added to a different database.⁶

Accordingly, please provide all records relating to the following:

- 1) All communications regarding the request to post the SARS-CoV-2 sequences to the Sequence Read Archive in March 2020. This request covers all communications between March 1, 2020 to March 31, 2020.
- 2) All communications regarding the request to withdraw the SARS-CoV-2 sequences from Sequence Read Archive in June 2020. This request covers all communications between June 1, 2020 to June 31, 2020.
- 3) All communications regarding these withdrawn sequences as reported by a preprint titled "Recovery of deleted deep sequencing data sheds more light on the early Wuhan SARS-CoV-2 epidemic" by Jesse Bloom, a virologist at the Fred Hutchinson Cancer Research Center.⁷ This request covers all communications between Jesse Bloom and the NIH, from January 1, 2021 and the present. This request all covers all communications inside the NIH regarding the preprint from June 21, 2021 to the present.
- 4) All communications to, from, and within the NIH press office about the NIH statement released on June 23, 2021, and about reports that these sequences were removed from the Sequence Read Archive. This includes all emails related to the drafting of the statement, communications about the reported removal, and communications with reporters. This request covers all communications between June 21, 2021 to June 25, 2021.

⁴ Id.

⁵ Id.

⁶ Id.

⁷ "Recovery of deleted deep sequencing data sheds more light on the early Wuhan SARS-CoV-2 epidemic," *bioRxiv* (Jun 18, 2021).

Fee Waiver Request

Empower Oversight requests a waiver of fees associated with processing this request, in keeping with 5 U.S.C. § 552 (a)(4)(A)(iii). The information sought is in the public interest because it is likely to contribute significantly to the public understanding of the operations or activities of the government. Empower Oversight is a non-profit organization as defined under Section 501(c)(3) of the Internal Revenue Code and has no commercial interest in making this request. The public has a significant interest in understanding how this pandemic started. Empower Oversight is committed to government accountability and public integrity and is committed to public disclosure of documents via its website, and by providing these documents to the media for public dissemination.⁸

Request for Expedited Processing

Empower Oversight also requests expedited processing of this request. Understanding how the SARS-CoV-2 pandemic started is of massive public interest both in the United States and around the globe, particularly because understanding how this pandemic started can help us stop future pandemics. The information requested is urgently needed to inform the public concerning actual or alleged federal government activity, namely why were genetic sequences removed from a United States federal database when they could help understand how the pandemic started. The request is of widespread and exceptional media interest and the information sought involves questions about research integrity, which affect public confidence in the operations of NIH. Empower Oversight is engaged in disseminating information to the public through its website and working with media.⁹ It is important that this request be processed and the results publicly disseminated as quickly as possible to help the country guard against future pandemics.

For ease of administration and to conserve resources, we ask that documents be produced in a readily accessible electronic format. In the event our request for a fee waiver is denied or if you have any questions about this request, please contact us immediately. Thank you for your prompt attention to this matter.

Cordially,

/Jason Foster/

Jason Foster Founder & President

⁸ "Mission," *Empower Oversight* (<u>http://empowr.us/mission</u>).

⁹ Id.

Exhibit 2



National Institutes of Health Freedom of Information Office Building 31, Room 5B-35 31 Center Drive, MSC 2107 Bethesda, Maryland 20892-2107 phone: (301) 496-5633 fax: (301) 402-4541

Via Email: info@empowr.us

February 7, 2022

Jason Foster Founder & President Empower Oversight 2615 Columbia Pike, #445 Arlington, VA 22204

Re: NIH FOIA Case No.: 56712 & 57203; Empower Oversight Whistleblowers & Research v. NIH, Case No. 21-cv-01275

Dear Mr. Foster:

This is the final response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in *Empower Oversight Whistleblowers & Research v. NIH*, Case No. 21-cv-01275, now pending in the U.S. District Court for Virginia. Your FOIA request 56712, dated July 15, 2021, was received by the National Institutes of Health (NIH) FOIA Office, on the same day. Your FOIA request 57203, dated October 12, 2021, was received by the National Institutes of Health (NIH) FOIA Office, on the same day.

FOIA request 56712 requested:

1)All communications regarding the request to post the SARS-CoV-2 sequences to the Sequence Read Archive in March 2020. This request covers all communications between March 1, 2020 to March 31, 2020.

2)All communications regarding the request to withdraw the SARS-CoV-2 sequences from Sequence Read Archive in June 2020. This request covers all communications between June 1, 2020 to June 31, 2020.

3)All communications regarding these withdrawn sequences as reported by a preprint titled "Recovery of deleted deep sequencing data sheds more light on the early Wuhan SARS-CoV-2 epidemic" by Jesse Bloom, a virologist at the Fred Hutchinson Cancer Research Center. This request covers all communications between Jesse Bloom and the NIH, from January 1, 2021 and the present. This request all covers all communications inside the NIH regarding the preprint from June 21, 2021 to the present.

4)All communications to, from, and within the NIH press office about the NIH statement released on June 23, 2021, and about reports that these sequences were removed from the Sequence Read Archive. This includes all emails related to the drafting of the statement, communications about the reported removal, and communications with reporters. This request covers all communications between June 21, 2021 to June 25, 2021.

1) All communications regarding the letter by Senators Grassley and Blackburn dated June 28, 2021.

2) All communications regarding the NIH's response to Senators Grassley and Blackburn dated September 8, 2021. 3) All communications regarding the letter by Senators Grassley and Blackburn dated September 16, 2021.

In accordance with the Court's order dated November 17, 2021, we have processed 255 pages of responsive records for this litigation. The information being withheld is protected from release pursuant to Exemptions (b)(5) and (b)(6) of the FOIA, 5 U.S.C. § 552 (b)(5) and (b)(6); and sections 5.31 (e) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making. Exemption 6 permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.

Please direct any questions regarding this response to Meghan Loftus of the Department of Justice, who can be reached at meghan.loftus@usdoj.gov.

Sincerely,

for Gorka Garcia-Malene Freedom of Information Act Officer, NIH