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0 7	Email: <u>kristina.morrison@usdoj.gov</u> Attorneys for the Defendant				
8	Auomeys jor me Dejenuum				
8 9	IN THE UNITED STATES DISTRICT COURT				
9 10	FOR THE DISTR	ICT OF ARIZONA			
10	Informed Consent Action Network,	CV-20-01277-JJT			
11	Plaintiff,	DEFENDANT'S ANSWER AND			
12	V.	AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT FOR			
13	National Institutes of Health,	DECLARATORY AND INJUNCTIVE RELIEF			
15	Defendant.				
16					
17	ANSWER TO COMPLAINT ¹ A	ND AFFIRMATIVE DEFENSES			
18	ANSWER TO COMPLAINT ¹ AND AFFIRMATIVE DEFENSES Pursuant to Rule 8, Federal Rules of Civil Procedure, Defendant National Institutes				
19		,			
20	of Health ("NIH"), by and through its attorneys, hereby responds to Plaintiff Informed				
21	Consent Action Network as follows: Introduction				
22	1. The allegations contained in Paragraph 1 do not set forth a claim for relief or				
23	aver facts in support of a claim to which a response is required. To the extent that a				
24	response is required, Defendant denies the allegations in Paragraph 1.				
25	2. Defendant admits that the National Institute of Allergy and Infectious				
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27	¹ For ease of reference. Defendant's Answer	generally replicates the headings contained in			
28	the Complaint. Although Defendant believes to the extent a response is deemed required a be construed to contain factual allegations, th	that no response is required to such headings, nd to the extent those headings and titles may			

Diseases ("NIAID") is an institute within NIH and that Dr. Anthony S. Fauci is NIAID's Director. Defendant further admits that NIAID has been funding and leading the development of mRNA-1273, the first vaccine for COVID-19 to enter into clinical trials. The remaining allegations of Paragraph 2 do not set forth a claim for relief or aver facts in support of a claim to which a response is required. To the extent that a response is required, Defendant denies those remaining allegations.

7 3. The allegations contained in Paragraph 3 consist of Plaintiff's 8 characterization of itself and do not set forth a claim or aver facts in support of a claim to 9 which a response is required. To the extent that a response is required, Defendant lacks 10 knowledge or sufficient information to form a belief as to the allegations, and therefore 11 denies the allegations.

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4. Defendant admits only that Plaintiff submitted the 13 FOIA requests to NIH, as detailed below:

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14				
15	REQUEST NUMBER	Dated	Request	Citation
16	Request	3/27/20	Copies of all and each Employee Invention	Exhibit A to
17	53821		Report related to any vaccine or therapeutic for	Plaintiff's
-			COVID-19.	Complaint,
18				Dkt. 1-1 at
19				3-4
	Request	3/27/20	Copies of any and all royalty or licensing	Exhibit B to
20	53822		agreements related to any vaccine or	Plaintiff's
21			therapeutic for COVID-19.	Complaint,
				Dkt. 1-1 at
22				6-7
23	Request	3/27/20	A copy of the page of any patent application	Exhibit C to
	53826		filed with regard to the mRNA-1273 vaccine	Plaintiff's
24			which lists the inventors.	Complaint,
25				Dkt. 1-1 at
		4 /0 /00		9-10
26	Request	4/9/20	All emails sent or received by Anthony Fauci	Exhibit D to
27	53963		between November 1, 2019 and the present that	Plaintiff's
			include the term Moderna or mRNA-1273 in	Complaint,
28			any portion of the email, including the body,	Dkt. 1-1 at

1			subject, metadata, sender line, or recipient line	12-13
			of the email, or any attachment to the email.	
2	Request	4/9/20	All emails sent or received by Barney Graham	Exhibit E to
3	53962		between November 1, 2019 and the present that	Plaintiff's
			include the term Moderna or mRNA-1273 in	Complaint,
4			any portion of the email, including the body,	Dkt. 1-1 at
5			subject, metadata, sender line, or recipient line	15-16
6	Request	4/9/20	of the email, or any attachment to the email. All emails sent or received by Kizzmekia	Exhibit F to
0	53961	4/9/20	Corbett between November 1, 2019 and the	Plaintiff's
7	55701		present that include the term Moderna or	Complaint,
8			mRNA-1273 in any portion of the email,	Dkt. 1-1 at
			including the body, subject, metadata, sender	18-19
9			line, or recipient line of the email, or any	
10			attachment to the email.	
	Request	4/9/20	All emails sent or received by Michael Gordon	Exhibit G to
11	53958		Joyce between November 1, 2019 and the	Plaintiff's
12			present that include the term Moderna or	Complaint,
12			mRNA-1273 in any portion of the email,	Dkt. 1-1 at
13			including the body, subject, metadata, sender	21-22
14			line, or recipient line of the email, or any	
15		4/0/20	attachment to the email.	F 11'4 H 4
	Request	4/9/20	All emails sent or received by Masaru Kanekiyo	Exhibit H to
16	53960		between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in	Plaintiff's Complaint,
17			any portion of the email, including the body,	Dkt. 1-1 at
			subject, metadata, sender line, or recipient line	24-25
18			of the email, or any attachment to the email.	2125
19	Request	4/9/20	All emails sent or received by Olubukola Mary	Exhibit I to
20	53959		Abisola Abiona between November 1, 2019 and	Plaintiff's
20			the present that include the term Moderna or	Complaint,
21			mRNA-1273 in any portion of the email,	Dkt. 1-1 at
22			including the body, subject, metadata, sender	27-28
			line, or recipient line of the email, or any	
23			attachment to the email.	
24	Request	4/29/20	All emails sent or received by Hadi Yassine	Exhibit J to
	54105		between November 1, 2019 and the present that	Plaintiff's
25			include the term Moderna or mRNA-1273 in	Complaint, Dkt. 1-1 at
26			any portion of the email, including the body, subject, metadata, sender line, or recipient line	30-31
			of the email, or any attachment to the email.	50-51
27	Request	4/29/20	All emails sent or received by Anthony Fauci	Exhibit K to
28	54106	1,27,20	between November 1, 2019 and the present that	Plaintiff's
	2 . 2 0 0	I		

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1			include the term SARS-CoV, COVID, COVID-	Complaint,
1			19 or coronavirus in any portion of the email,	Dkt. 1-1 at
2			including the body, subject, metadata, sender	33-34
3			line, or recipient line of the email, or any	
3			attachment to the email.	
4	Request	4/29/20	All emails sent or received by Barney Graham	Exhibit L to
5	54107		between November 1, 2019 and the present that	Plaintiff's
5			include the term SARS-CoV, COVID, COVID-	Complaint,
6			19 or coronavirus in any portion of the email,	Dkt. 1-1 at
7			including the body, subject, metadata, sender	36-37
/			line, or recipient line of the email, or any	
8			attachment to the email.	
0	Request	5/22/20	All safety and efficacy data and information	Exhibit M to
9	54464		regarding mRNA-1273, including from the	Plaintiff's
10			Phase I clinical trial of this experimental	Complaint,
			vaccine conducted by the National Institute of	Dkt. 1-1 at
11			Allergy and Infectious Diseases.	39-40

13 Defendant respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a 14 complete and accurate description of their contents. Defendant further admits that NIH 15 granted expedited processing for Request 54464. NIH denies the allegation that NIH failed 16 to further respond to Plaintiff's requests. In addition, Defendant lacks knowledge or 17 sufficient information to form a belief as to the allegations pertaining to Plaintiff's mission 18 or acts pertaining to inquiries it received, and therefore denies those allegations.

5. Defendant admits that it has not yet provided a final determination letter or produced any documents in response to Plaintiff's 13 FOIA requests, as it is still processing those requests. The remaining allegations contained in Paragraph 5 consist of Plaintiff's characterization of its FOIA requests, its motive in bringing this action, and its conclusions of law, to which no response is required.

Defendant denies those allegations.

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Parties

To the extent that a response is required,

26 6. The allegations contained in Paragraph 6 contain Plaintiff's characterization 27 of itself. Defendant lacks knowledge or sufficient information to form a belief as to the 28 allegations, and therefore denies the allegations.

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1 7. Admit. 2 Jurisdiction and Venue 3 8. Paragraph 8 is a statement pertaining to jurisdiction and venue, to which no 4 response is required. To the extent that a response is required, Defendant denies the 5 allegations in Paragraph 8. 6 <u>Facts</u> 7 9. Admit. 8 10. Paragraph 10 is duplicative of Paragraph 9, and Defendant therefore relies 9 on its response to Paragraph 9. 10 11. Defendant admits that NIAID used taxpayer dollars to sponsor, assume 11 responsibility for, and perform the first clinical trial for the mRNA-1273 vaccine. 12 Defendant denies the remaining allegations in Paragraph 11. 13 12. Defendant lacks knowledge or sufficient information to form a belief as to 14 the allegations, which are vague and ill-defined, and therefore denies the allegations. 15 13. Defendant admits that provisional applications 62/972,886 ("2019-nCoV 16 Vaccine") and 62/412,703 ("Prefusion Coronavirus Spike Proteins and Their Use") have 17 been filed. Defendant lacks knowledge or sufficient information to form a belief as to the 18 remaining allegations in Paragraph 13, and therefore denies the remaining allegations. 19 14. The allegations contained in Paragraph 14 consist of Plaintiff's conclusions 20 of law, to which no response is required. To the extent that a response is required, 21 Defendant denies the allegations. 22 15. The allegations contained in Paragraph 15 do not set forth a claim or aver 23 facts in support of a claim to which a response is required. To the extent that a response is 24 required, Defendant lacks knowledge or sufficient information to form a belief as to the 25 allegations, and therefore denies the allegations. 26 16. The allegations contained in Paragraph 16 do not set forth a claim or aver 27 facts in support of a claim to which a response is required. To the extent that a response is 28 required, Defendant lacks knowledge or sufficient information to form a belief as to the

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allegations, and therefore denies the allegations.

17. The allegations contained in Paragraph 17 contain legal conclusions and do not set forth a claim or aver facts in support of a claim to which a response is required. To the extent that a response is required, Defendant lacks knowledge or sufficient information to form a belief as to the allegations, and therefore denies the allegations.

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The FOIA Requests

18. Admit.

8 19. Defendant admits that Plaintiff submitted each of the listed FOIA requests to 9 NIH and respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a complete 10 and accurate description of their contents. However, Defendant denies that Requests 11 53963, 53962, 53961, 53958, 53960, 53959 and 54105 were dated April 10, 2020.

12 20. Defendant admits that Plaintiff submitted each of the listed FOIA requests to
13 NIH and respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a complete
14 and accurate description of their contents. However, Defendant denies that Requests 54106
15 and 54107 were dated May 5, 2020.

16 21. Defendant admits only that Plaintiff submitted Request 54464 on May 22,
17 2020 and Plaintiff requested expedited processing for this request. Plaintiff's
18 characterization of the requested information as "critical" and "specific" calls for legal
19 conclusions, and Defendant therefore denies these allegations.

20 22. The allegations contained in Paragraph 22 consist of Plaintiff's conclusions
21 of law, to which no response is required. To the extent that a response is required,
22 Defendant denies the allegations.

23 23. The allegations contained in Paragraph 22 consist of Plaintiff's conclusions
24 of law, to which no response is required. To the extent that a response is required,
25 Defendant denies the allegations.

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II.

NIH (Allegedly) Fails to Properly Respond or Produce Any Documents²

24. The allegations contained in Paragraph 24 consist of Plaintiff's conclusions of law, to which no response is required. To the extent that a response is required, Defendant denies the allegations.

5 25. Defendant admits only that it sent Plaintiff correspondence regarding each of 6 the listed FOIA requests and respectfully refers the Court to the correspondence (Dkt. 1-1 7 at 42-68) for a complete and accurate description of their contents. Defendant denies all 8 other allegations, including any characterizations as to the sufficiency of the 9 correspondence, in Paragraph 25.

26. Defendant admits only that it sent Plaintiff correspondence regarding
Request 54464 and respectfully refers the Court to the correspondence (Dkt. 1-1 at 67-68)
for a complete and accurate description of its contents. Defendant denies all other
allegations, including any characterization of NIH's interpretation of the request, in
Paragraph 26.

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27. Admit.

16 28. The allegations contained in Paragraph 28 consist of Plaintiff's conclusions
17 of law, to which no response is required. To the extent that a response is required,
18 Defendant denies the allegations.

19 29. The allegations contained in Paragraph 29 consist of Plaintiff's conclusions
20 of law, to which no response is required. To the extent that a response is required,
21 Defendant denies the allegations.

30. The allegations contained in Paragraph 30 consist of Plaintiff's conclusions
of law, to which no response is required. To the extent that a response is required,
Defendant denies the allegations.

- 25 31. The allegations contained in Paragraph 31 consist of Plaintiff's conclusions
 26 of law, to which no response is required. To the extent that a response is required,
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² This header is an argumentative and conclusory statement, and Defendant denies it as such.

Defendant denies the allegations.

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REQUESTED RELIEF

3 The remainder of the Complaint consists of Plaintiff's Prayer for Relief, to which 4 no response is required. To the extent that a response is required, Defendant incorporate 5 by reference the responses to all preceding paragraphs, and denies the allegations in the 6 Prayer for Relief, and denies that Plaintiff is entitled to any of the relief requested in 7 Paragraphs 1 through 31, or to any relief whatsoever from the Defendant. 8 9 **AFFIRMATIVE DEFENSES** 10 FIRST AFFIRMATIVE DEFENSE 11 1. Plaintiff's Complaint fails to state a claim upon which relief may be granted. 12 SECOND AFFIRMATIVE DEFENSE 13 2. Any information that Defendant have withheld, or will withhold, in response 14 to Plaintiff's FOIA request may be exempt in whole or in part from public disclosure under 15 the FOIA, 5 U.S.C. § 552 et seq., and the Privacy Act, 5 U.S.C. § 552(a), et seq. 16 THIRD AFFIRMATIVE DEFENSE 17 3. The Court lacks jurisdiction over any matter to the extent Plaintiff failed to 18 satisfy prerequisites to suit, as well as over any requests or allegations that are not contained 19 in the FOIA request at issue in this action. 20 FOURTH AFFIRMATIVE DEFENSE 21 4. Plaintiff has not alleged sufficient factual and/or legal bases for its request 22 for costs and/or attorney's fees. 23 FIFTH AFFIRMATIVE DEFENSE 24 5. Plaintiff's request submitted under FOIA, 5 U.S.C. § 552, as amended, did 25 not reasonably describe the records sought. 26 27 28

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SIXTH AFFIRMATIVE DEFENSE

6. There is no provision of the FOIA for obtaining declaratory relief. At all times alleged in the Complaint, Defendant were acting in good faith, with justification, and pursuant to authority.

SEVENTH AFFIRMATIVE DEFENSE

7. All proceedings with respect to Plaintiff's FOIA requests should be stayed pending further order of this Court to be issued after those requests reach, in the normal course of business, the front of the processing queue to which they are assigned.

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EIGHTH AFFIRMATIVE DEFENSE

8. Defendant have exercised due diligence in processing Plaintiff's FOIA
requests, and exceptional circumstances exist that necessitate additional time for Defendant
to continue its processing of Plaintiff's FOIA requests. See 5 U.S.C. § 552(a)(6)(C).

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NINTH AFFIRMATIVE DEFENSE

14 9. Upon information and belief, Plaintiff has not perfected service on 15 Defendant. Although Plaintiff has served the United States Attorney's Office in the 16 District of Arizona and the Attorney General, it does not appear that Plaintiff has served 17 the agency, as required under Rule 4(i)(2). Nor has Plaintiff filed the required proof of 18 service. Fed. R. Civ. P. 4(1). NIH does not waive, but expressly preserves this defense. 19 Dismissal is warranted should Plaintiff fail to effect service within 90 days of having filed 20 the complaint. Fed. R. Civ. P. 4(m).

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10. Defendant respectfully request and reserve the right to amend, alter, and
supplement the defenses contained in this Answer as the facts and circumstances giving
rise to the Complaint become known through the course of litigation.

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PRAYER FOR RELIEF

- WHEREFORE, Defendant prays that:
 - 1. Plaintiff take nothing by its Complaint;

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1	2. The Complaint be dismissed with prejudice;
2	3. No injunction relief be awarded to Plaintiff;
3	4. Defendant be awarded the costs of suit;
4	5. Judgment be entered in favor of Defendant;
5	6. The Court grant such other and further relief as it may deem proper.
6	
7	Respectfully submitted this 10th day of August 2020.
8	
9	MICHAEL BAILEY United States Attorney
10	District of Arizona
11	<u>s/Kristina L. Morrison</u> KRISTINA L. MORRISON
12	Assistant U.S. Attorney Attorneys for Defendant NIH
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CERTIFICATE OF SERVICE

1	CERTIFICATE OF SERVICE
2	I hereby certify that on August 10, 2020, I electronically transmitted the attached
3	document to the Clerk's Office using the CM/ECF System for filing and transmittal of a
4	Notice of Electronic Filing to the following CM/ECF registrant(s):
5	
6	AARON SIRI, AZ Bar No. 035890 SIRI & GLIMSTAD LLP
7	11201 North Tatum Boulevard, Suite 300
8	Phoenix, AZ 85028 Tel: (602) 806-9975
9	aaron@sirillp.com
10	ELIZABETH A. BREHM, pro hac vice to be filed
11	SIRI & GLIMSTAD LLP
12	200 Park Avenue, 17th Floor New York, NY 10166
13	Tel: (212) 532-1091
14	ebrehm@sirillp.com Attorneys for Plaintiff
15	
16	s/ Irene Millsaps
17	United States Attorney's Office
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