IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH RESEARCH GROUP, 1600 20th Street NW Washington, DC 20009, Plaintiff, v. DEPARTMENT OF HEALTH & HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201, Defendant.	Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiff Public Citizen Health Research Group ("HRG") brings this action under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), to compel the Department of Health and Human Services ("HHS") to produce records in response to five FOIA requests. In these requests, HRG requested documents concerning two clinical trials supported by the National Institutes of Health ("NIH") testing experimental treatments in extremely premature babies: the Surfactant, Positive Pressure, and Pulse Oximetry Randomized Trial ("SUPPORT") and the Transfusion of Prematures ("TOP") trial.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B). Venue is proper under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff HRG is an arm of the nonprofit research and consumer advocacy organization Public Citizen, which represents the public interest before Congress, the executive branch, and the courts. HRG promotes research-based, system-wide changes in healthcare policy and drug safety. HRG also works to have unsafe or ineffective drugs and medical devices banned or re-labeled, to reduce worker exposures to hazardous chemicals, and to educate the public about dangerous drugs and drug interactions through its newsletters and WorstPills.org.

4. Defendant HHS is an agency of the United States. HHS has possession of and control over the records Plaintiff seeks.

5. NIH is located within HHS. HHS processes FOIA appeals for NIH.

6. The National Institute of Child Health and Human Development (NICHD) is one of the 21 Institutes that make up the National Institutes of Health.

FACTUAL BACKGROUND

The Neonatal Research Network

7. The NICHD Neonatal Research Network (NRN) is "a collaborative network of neonatal intensive care units across the United States." Neonatal Research Network Overview, https://www.nichd.nih.gov/research/supported/Pages/nrn.aspx (last visited Mar. 2, 2016). At present, the NRN is composed of 18 clinical centers and a data coordinating center. *Id.* The NRN has completed or is currently conducting 18 observational studies and 34 clinical trials. *Id.*

The SUPPORT Clinical Study

8. Between 2005 and 2009, the NRN conducted the SUPPORT study. NIH funded the SUPPORT study.

9. For many years, researchers have known that the amount of oxygen used to treat premature babies impacts the health outcomes for those infants: too much oxygen increases the risk of blindness in infants, but too little oxygen can cause other problems, such as brain damage or death. SUPPORT Study Group of the Eunice Kennedy Shriver NICHD Neonatal Research Network, *Target Ranges of Oxygen Saturation in Extremely Preterm Infants*, 362 New Eng. J. Med. 1959, 1959-60 (May 27, 2010), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMoa0911781; *see also* Letter from HRG to Kathleen Sebelius, Secretary of HHS (April 10, 2013), at 2, *available at* http://www.citizen.org/documents/2111.pdf. The SUPPORT study was designed to determine precisely how much oxygen to use to minimize these competing risks.

10. Collaborating neonatal intensive care units in the NRN enrolled over 1,300 infants in the trial.

11. In 2013, the Office of Human Research Protections (OHRP), an office within HHS that provides regulatory oversight over biomedical and behavioral human subjects research, sent a letter to the lead institution for the SUPPORT study stating that the informed consent forms did not adequately warn about the risks of blindness, neurological damage, and death. Letter from OHRP to the Univ. of Ala. at Birmingham (March 7, 2013), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR13/mar13a.pdf.

The TOP Clinical Study

12. The NRN is currently conducting the TOP clinical trial. NIH is funding the TOP trial.

13. The goal of the TOP trial is to determine which of two strategies for treating anemia with blood transfusions is more likely to result in death or neurologic injury in extremely premature infants who develop anemia. Haresh Kirpalani et al., TOP Trial Protocol at 1, Oct. 8,

2012, *available at* https://www.nichd.nih.gov/about/Documents/TOP_Protocol.pdf. Anemia is a condition caused by low blood hemoglobin, a component of red blood cells that carries oxygen from the lungs to other organs in the body. The study randomly assigns babies to one of two groups: the liberal transfusion group, which receives transfusions when the anemia is relatively mild, or the restrictive transfusion group, which receives transfusions only once the anemia is severe. *Id.* The NRN clinical sites seek to enroll over 1,800 infants in the trial. ClinicalTrials.gov: TOP trial, https://clinicaltrials.gov/ct2/show/NCT01702805.

14. HRG called on HHS to halt the TOP trial because the consent forms do not adequately disclose the potential risks to infants in the trial and because of ethical concerns about the design of the study. Letter from HRG to Kathleen Sebelius, Secretary of HHS (Aug. 22, 2013), *available at* http://www.citizen.org/documents/2150.pdf; *see also* Richard Knox, *Another Study Of Preemies Blasted Over Ethical Concerns*, Nat'l Pub. Radio, Aug. 23, 2013, http://n.pr/14KSIQp.

NIH Cooperative Agreements

15. NIH funded both the SUPPORT and TOP studies through cooperative agreement awards to the participating clinical sites. Cooperative Multicenter Neonatal Research Network, Request for Applications: RFA-HD-00-010, Apr. 3, 2000, http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-00-010.html (reissued in 2005 and 2010). Under cooperative agreements, NIH's role is "to support" and "stimulate" the award recipients' activities and work "jointly with the award recipients in a partner role." *Id.* NIH's role is "not to assume direction, prime responsibility, or a dominant role in the activity." *Id.* Instead, "prime responsibility" for the study belongs to the award recipients. *Id.*

Plaintiff's First Request

16. By letter dated April 18, 2013, HRG submitted a FOIA request to NICHD seeking (1) all documents and correspondence "regarding the development, review, clearance or approval" of the SUPPORT study, and (2) all records of all NIH meetings "related to the development, review, clearance or approval of the SUPPORT study." HRG also requested a public interest fee waiver, 5 U.S.C. § 552(a)(4)(A)(iii).

17. In response to Item 1 of the request, NICHD made four partial releases of documents to HRG from May through July 2013. Additionally, NICHD stated that it had referred 738 pages of responsive records to NIH's FOIA Office "for their release determination and direct response to you."

18. By letter dated March 20, 2014, NIH's FOIA Office provided a final response to HRG's April 18, 2013, FOIA request. In response to Item 1 of the request, NIH released 348 additional pages, with redactions, but withheld portions of those pages under FOIA exemptions 5 and 6, and also withheld portions that it deemed to contain "information outside the scope" of HRG's request. NIH withheld approximately 382 pages in their entirety as "consisting of draft documents."

19. NIH also stated that because "no unusual circumstances apply to the processing of your request, there is no charge associated with our response."

20. By letter dated April 22, 2014, HRG timely appealed NIH's adverse determination in full to HHS.

21. In a letter dated October 14, 2015, HHS denied the appeal. HHS stated that the records it withheld under exemption 5 qualified as being inter- or intra- agency records because

the Principal Investigators of the NRN are "expert consultants" and "advisors to NICHD" and those experts "are not communicating at the expense of other applicants."

Plaintiff's Second Request

22. By letter dated June 10, 2013, HRG requested from NIH: (1) all correspondence and other records of communication between NIH and OHRP or HHS's Office of the Secretary since February 1, 2013, and related to the SUPPORT study (denoted as Items 1 and 2 in the request); and (2) all correspondence and other records of communication between NIH and OHRP or HHS's Office of the Secretary since February 1, 2013, and related to OHRP's compliance oversight procedures and activities (denoted as Items 3 and 4 in the request). HRG also requested a public interest fee waiver, 5 U.S.C. § 552(a)(4)(A)(iii).

23. By letter dated June 13, 2013, NIH acknowledged receipt of HRG's request.

24. By letter dated March 25, 2014, HHS released records responsive to Items 1 and 2 of the request, but failed to release any records responsive Items 3 and 4. HHS's response apprised HRG of its FOIA appeal rights.

25. HHS did not address the fee waiver request, but did not charge a fee.

26. By letter dated April 22, 2014, HRG timely appealed HHS's adverse determination in full. HRG appealed the adequacy of the agency's search because it had failed to produce any records responsive to Items 3 and 4.

27. By email sent on April 22, 2014, HHS acknowledged receipt of the appeal.

28. To date, HHS has not substantively responded to HRG's April 22, 2014, appeal.

Plaintiff's Third Request

29. By letter dated March 28, 2014, HRG requested from NIH all correspondence and other records of communications (1) between NIH and OHRP or HHS's Office of the Secretary

since June 10, 2013, and related to the SUPPORT study; and (2) between NIH and OHRP or HHS's Office of the Secretary since April 1, 2013, and related to the TOP trial or any other NICHD NRN clinical trial. HRG also requested a public interest fee waiver, 5 U.S.C. § 552(a)(4)(A)(iii).

30. By letter dated April 2, 2014, NIH acknowledged receipt of the request.

31. By letter dated November 14, 2014, NIH issued a "final response" to the March 28, 2014, FOIA request. NIH stated that its search had "produced records that fall under the jurisdiction of HHS." NIH explained that it had referred the records to HHS's FOIA Office "for review, determination of releasability and direct response to you."

32. The letter stated that if there were any fees associated with processing the request, HHS would send an invoice with its final response.

33. By letter dated November 23, 2015, HHS acknowledged receipt of HRG's March 28, 2014, request, which NIH had forwarded.

34. By letter dated December 31, 2015, HHS provided an "interim response" to the March 28, 2014, request.

35. HHS stated that it had located 425 pages of responsive records. It released 256 pages in their entirety and 88 pages with redactions pursuant to exemption 5 and 6. HHS withheld 67 pages in their entirety.

36. HHS also stated that HRG's request was "still pending" and that the "remaining 14 pages of responsive records are under review." HHS stated that the interim response could not be appealed until the agency issued a final response.

37. To date, HHS has not released the remaining 14 pages or issued a final appealable response to HRG's March 28, 2014, request.

Plaintiff's Fourth Request

38. By letter dated May 22, 2014, HRG requested from NIH all correspondence and records of communication since July 18, 2011, related to the SUPPORT study (1) between NIH employees and (2) between NIH employees and any individual, institution or other entity external to HHS. HRG also requested a public interest fee waiver, 5 U.S.C. § 552(a)(4)(A)(iii).

39. By letter dated May 30, 2014, NIH acknowledged receipt of the request.

40. By letter dated September 14, 2015, NIH issued a "final response" to the May 22, 2014, FOIA request. NIH stated that its search produced approximately 16,450 pages of responsive records "consisting of email discussions with draft documents between NIH Officials, and between NIH Officials and HHS Officials." NIH explained that it "does not have jurisdiction over HHS records" and therefore, that it had "forwarded your request and the responsive records to HHS's FOIA Office for further review, determination of releasability and direct response to you."

41. The letter stated that if there were any fees for processing the May 22 request, HHS would send an invoice "with the HHS final response." NIH's letter did not provide appeal rights.

42. By email on September 24, 2015, HRG asked NIH why it could not release the subset of responsive records that are not "HHS records."

43. By email on September 25, 2015, NIH responded that "[b]ecause the topics are similar and overlap, and interface with HHS records, we cannot breakout NIH only materials from HHS materials."

44. By letter dated September 29, 2015, HHS acknowledged receipt of HRG's May 22, 2014, FOIA request, which NIH had forwarded.

45. To date, HHS has not substantively responded to HRG's May 22, 2014, request and has not produced any records in response to the request.

Plaintiff's Fifth Request

46. By letter dated October 30, 2015, HRG requested from NICHD all documents and correspondence regarding the SUPPORT study that were created from December 2004 through May 31, 2010, including correspondence sent to or received from individuals external to NIH. HRG requested a public interest fee waiver of all fees in connection with its request, 5 U.S.C. § 552(a)(4)(A)(iii).

47. By letter dated October 30, 2015, NICHD acknowledged receipt of the FOIA request.

48. By email sent on December 14, 2015, NICHD asked whether HRG would amend its request to exclude budget and funding records. In an email sent that same day, HRG agreed to exclude those records from its request.

49. To date, NICHD has not substantively responded to HRG's fifth request or its request for a fee waiver, and it has not produced records in response to its fifth request.

FOIA's Time Limits

50. Under 5 U.S.C. § 552(a)(6)(A)(i), NIH had 20 working days to respond to HRG's FOIA requests. More than 482 days have passed since NIH received HRG's third request of March 28, 2014. More than 446 days have passed since NIH received HRG's fourth request of May 22, 2014. More than 86 days have passed since NIH received HRG's fifth request of October 30, 2015.

51. Under 5 U.S.C. § 552(a)(6)(A)(ii), HHS had 20 working days to respond to HRG's appeal of its second request of June 10, 2013. More than 469 days have passed since HHS received HRG's appeal with respect to the second request.

52. HRG has exhausted its administrative remedies with respect to all five requests.

FIRST CLAIM FOR RELIEF

53. Plaintiff has a statutory right under FOIA, 5 U.S.C. § 552(a)(3)(A), to the entirety of records it requested in Item 1 of its first request and in Items 3 and 4 of its second request. Plaintiff has a statutory right under FOIA to the entirety of records requested in its third, fourth, and fifth requests. No legal basis exists for Defendant's withholding of the records in full or in part.

SECOND CLAIM FOR RELIEF

54. Under 5 U.S.C. § 552(a)(4)(A)(iii), Plaintiff is entitled to a full waiver of fees that otherwise would be assessed in conjunction with its requests. The failure to grant Plaintiff's requests for a public interest fee waiver with respect to its second, third, fourth, and fifth requests violates FOIA.

PRAYER FOR RELIEF

Wherefore, Plaintiff requests that this Court:

A. Declare that Defendant's withholding of the requested records is unlawful under FOIA;

B. Order Defendant to make the requested material available to Plaintiff at no charge within 14 days of the Court's order;

C. Award Plaintiff its costs and reasonable attorney fees under 5 U.S.C. § 552(a)(4)(E); and

D. Grant all other appropriate relief.

Dated: March 8, 2016

Respectfully submitted,

/s/ Rachel M. Clattenburg
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