

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITE COAT WASTE PROJECT, INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 22-0006 (CJN)

DEFENDANTS' MOTION TO DISMISS

Defendants the U.S. Department of Health and Human Services and the National Institutes of Health (collectively, “Defendants”), by and through undersigned counsel, respectfully move to dismiss the Complaint filed by the White Coat Waste Project, Inc. (“Plaintiff”) pursuant to Federal Rules of Civil Procedure (“Rules”) 12(b)(1) and 12(b)(6).

The Complaint is subject to dismissal as Plaintiff lacks Article III standing to bring its claims under the Administrative Procedure Act (“APA”). Specifically, Plaintiff lacks organizational and representational standing to challenge the agency policies and guidance at issue. Additionally, Plaintiff fails to allege a deprivation of information that they are entitled to receive by statute. For these same reasons, Plaintiff also fails to adequately plead procedural standing for its alternative claim for relief. Finally, Plaintiff fails to state a claim under the APA because it fails to assert an interest that is protected by the statute at issue.

A memorandum of points and authorities accompanies this motion. A proposed form of order is also included.

Dated: September 20, 2022

Respectfully submitted,

MATTHEW M. GRAVES
D.C. Bar No. 481052
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

By: /s/ Michael E. Yohannan
MICHAEL E. YOHANNAN
Pennsylvania Bar Number 307575
Special Assistant United States Attorney
U.S. Attorney's Office, Civil Division
601 D Street, N.W.
Washington, D.C. 20530
Tel: (202) 815-8969
Michael.Yohannan@usdoj.gov

Counsel for Defendants

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**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
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MATTHEW M. GRAVES

United States Attorney

BRIAN P. HUDAK

Chief, Civil Division

MICHAEL E. YOHANNAN

Special Assistant United States Attorney

U.S. Attorney's Office for the District of Columbia

September 20, 2022

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Plaintiff, the White Coat Waste Project, Inc. (“White Coat”), is a “bipartisan taxpayer watchdog organization.” ECF No. 17 Amended Complaint (“Am Compl.”) ¶ 6. White Coat’s “mission is to unite animal-lovers and liberty-lovers to find, expose, and defund wasteful and cruel taxpayer-funded animal experimentation.” *Id.* In this action, White Coat challenges policies and external guidance that Defendants issued or promulgated pursuant to Section 495 of the Public Health Services Act (“Services Act”) (42 U.S.C. § 289d). Services Act Section 495 provides that the Secretary of Health and Human Services (the “Secretary”) must establish guidelines for the proper care and use of animals used in biomedical and behavioral research that is funded by the National Institutes of Health (“NIH”) or any other national research institution. *Id.* § 289d(a). The grant applicant must submit “assurances” to NIH that it complies with the guidelines for the care and use of laboratory animals and NIH must deem the assurance satisfactory for the grant applicant to remain eligible for NIH funding. *Id.* at § 289d(c)-(d). Specifically, White Coat challenges the NIH guidance that allows a foreign grant applicant to obtain approval of an animal welfare assurance without organizing an entity called an Institutional Animal Care and Use Committee (“Institutional Animal Committee”).

White Coat does not claim to have ever applied for a research grant from NIH, nor that it conducts any medical research at all. Rather, White Coat asserts that NIH’s application of the animal welfare assurance requirement of Services Act Section 495 to foreign institutions “directly conflicts with, impairs, and frustrates its organizational mission and has required [White Coat] to divert and redirect its limited resources to counteract and offset Defendants’ unlawful actions and omissions.” Am Compl. ¶ 7. White Coat further asserts that the NIH guidance on animal welfare assurances for foreign grant applicants causes White Coat “a

significant and irreparable informational injury” because it is not able to obtain unspecified information about the use of laboratory animals by foreign grant applicants. *Id.*

White Coat brings this action under the Administrative Procedure Act (“APA”) (5 U.S.C. § 701 *et seq.*) and asks the Court to declare that Defendants exceeded their statutory authority when they issued guidance pursuant to Services Act Section 495 that allows foreign institutions to obtain an animal welfare assurance without organizing an Institutional Animal Committee. White Coat claims that portions of four separate publications that describe or implement this guidance to foreign grant applicants violate the APA. The NIH publications at issue in this case are: (1) Section II of the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (“Humane Care Policy”); (2) Section 4.1.1.4 of the NIH Grants Policy Statement; (3) a NIH website containing instructions for foreign institutions seeking an animal welfare assurance that White Coat refers to as the “Foreign Grants Website.”¹; and (4) a NIH website containing instructions for foreign Public Health Service grant applicants on obtaining an animal welfare assurance (“Foreign Animal Welfare Assurance Guidance”)² Am. Compl. ¶¶ 25, 30-31, 33, 43.

The Court should dismiss Plaintiff’s Complaint under 12(b)(1) because Plaintiff lacks standing to bring any of its claims under the APA. First, Plaintiff cannot maintain this action because it fails to allege facts sufficient to establish organizational or representational standing.

¹ Foreign Grants – Animal Welfare, https://grants.nih.gov/grants/foreign/animal_welfare.htm (last visited Sept. 20, 2022).

² Foreign Assurance, <https://olaw.nih.gov/resources/documents/foreign.htm> (last visited Sept. 20, 2022). The Amended Complaint refers to this website as “the Foreign Animal Welfare Assurance Rules” however this is not the title of the website and nowhere on the website does NIH refer to any of its guidance this way.

Second, Plaintiff fails to allege an informational injury sufficient to establish standing because Plaintiff has not identified what information Defendants have failed to provide, why White Coat is legally entitled to receive such information, or how this causes White Coat a concrete and particularized injury. Should the Court reach Plaintiff's alternative claims for relief, such claims should be dismissed because White Coat lacks standing to assert a procedural claim under the APA without a concrete injury in fact that could be redressed by the relief it seeks.³ Alternatively, the Court should dismiss the Amended Complaint under 12(b)(6). The Amended Complaint fails to state a claim under the APA because the claims Plaintiff attempts to assert in this action fall outside the Services Act's zone of interests.

BACKGROUND

A. THE ANIMAL WELFARE ASSURANCE REQUIREMENT OF THE PUBLIC HEALTH SERVICE ACT

The Services Act was amended in 1985 by the Health Research and Extension Act, which required the Secretary to establish guidelines for the humane care and use of animals used in NIH funded biomedical and behavioral research. Pub. L. No. 99-158, § 495(a) (codified as 42 U.S.C. § 289d(a)). As amended, the Services Act requires that institutions receive NIH approval of its assurances that it complies with these animal care guidelines when NIH funding would support research involve the use of laboratory animals. *Id.* at §495(c), 99 Stat. at 876. Pursuant to 42 U.S.C. § 289d(a), the Secretary of Health and Human Services promulgated the Humane Care Policy. The Humane Care Policy instructs that institutions whose animal care

³ Local Civil Rule 7(n) requires that, in APA cases, the agency must file a certified copy of the administrative record when the agency files a dispositive motion. *See* LCvR 7(n). However, given that Defendant's current dispositive motion focuses entirely on purely legal issues—namely, Plaintiff's lack of standing to sue, an administrative record is unnecessary for the Court to rule on this threshold issue. Accordingly, concurrently herein, Defendants separately move to be excused from Local Rule 7(n)'s requirements or, alternatively, to stay the submission of the certified list of the administrative record until the Court resolves this dispositive motion.

committee is an “Institutional Animal Care and Use Committee” seek approval of an animal welfare assurance through an “institutional official” and sets forth the role of the Institutional Animal Committee in acting as an agent for the institution that monitors the institution’s use of animals in research funded by the Public Health Service. *See* Humane Care Policy Sec. IV.A-B. The Humane Care Policy provides that the Institutional Animal Committee will prepare certain reports for the Institutional Official and that some reports are submitted by the Institutional Official to NIH and other are made available to NIH upon request. *Id.* at Sec. IV.B, F. NIH is responsible for approving animal welfare assurances. *See Id.*, Preface.

NIH guidance is clear that both domestic and foreign institutions that propose to use animals in Public Health Service funded research must have their animal welfare assurance approved by NIH to receive funding for research involving animals. *See generally* Humane Care Policy at Sec. IV.A. (“No activity involving animals may be conducted or supported by the [Public Health Service] until the institution conducting the activity has provided a written Assurance acceptable to the [Public Health Service], setting forth compliance with the Policy”). Per Section II of the Humane Care Policy, institutions in the United States, Puerto Rico, and U.S. territories are required to follow the procedures described in the Humane Care Policy to obtain NIH approval of an animal welfare assurance. Practically, this means that such institutions are required to obtain such approval after a review by their Institutional Animal Committees which, pursuant to the Humane Care Policy, must review the institution’s use and care of laboratory animals that are to be used in Public Health Service funded research.

NIH has established an alternate application process for foreign institutions to receive approval of their animal welfare assurance. *See* NIH Foreign Assurance, <https://olaw.nih.gov/resources/documents/foreign.htm> (last visited Sept. 20, 2022). A foreign institution may obtain

approval of its animal welfare assurance either through the Institutional Animal Committee procedures in the Humane Care Policy or by submitting evidence to NIH that its proposed use of animals in NIH funded research would be sufficiently humane. *See* Humane Care Policy, Section II. The foreign institution seeking approval of an animal welfare assurance without an Institutional Animal Committee (a “foreign assurance”) must also commit to following the International Guiding Principles for Biomedical Research Involving Animals and any laws on the welfare of laboratory animals that apply in the institution’s local jurisdiction. *See* Foreign Grants Website.

B. THE INSTANT LAWSUIT

On August 5, 2022, Plaintiff filed its Amended Complaint in the instant lawsuit against the Department of Health and Human Services and NIH, alleging that specific provisions of the Humane Care Policy, the Grants Policy Statement and other NIH guidance for foreign institutions applying for grants violates the APA. *See generally* Am. Compl. The amended complaint alleges that “NIH enacted multiple and binding agency rules” exempting foreign grant recipients of NIH funding from using an animal care committee to monitor the institution’s compliance with standards for the welfare of any laboratory animals used in NIH funded research. Am. Compl. ¶ 1. Alternatively, Plaintiff alleges that the above-referenced provisions of the Grants Policy Statement, the Humane Care Policy and the guidance for foreign grant applicants constituted rule making within the meaning of the APA and were therefore subject to the notice and comment requirements of 5 U.S.C. § 553. Am. Compl. ¶ 3.

Plaintiff seeks the following relief: (1) “declaratory judgment that Defendants have violated the APA by exceeding their statutory authority through agency actions . . . including, at a minimum, the [Institutional Animal Committee] exemption of NIH Grants Policy Statement Sec. 4.1.1.4, the [Institutional Animal Committee] [e]xemption of the [Humane Care Policy], the

[Institutional Animal Committee] exemption on the NIH Foreign Grants website, the [Institutional Animal Committee] exemption of the Foreign Animal Welfare Assurance Rules, and any equivalent agency rules, requirements, and publications;” (2) “an order vacating and setting aside agency actions violating 42 U.S.C.A. §§ 289d(b)(1), (c)(1)(A) including, at a minimum, the [Institutional Animal Committee] exemption of NIH Grants Policy Statement Sec. 4.1.1.4, the [Institutional Animal Committee] [e]xemption of the [Humane Care Policy], the [Institutional Animal Committee] exemption on the NIH Foreign Grants website, the [Institutional Animal Committee] exemption of the Foreign Animal Welfare Assurance Rules, and any equivalent agency rules, requirements, and publications and enjoining Defendants from using the Foreign Animal Lab Loophole, or any substantive equivalent”; (3) “an order vacating and setting aside any awards of taxpayer funding and/or animal welfare assurances granted in violation of 42 U.S.C.A. §§ 289d(b)(1), (c)(1)(A).” Am. Compl. at 31-32, ¶¶ A, B, C.

Alternatively, Plaintiff seeks (4) “a declaratory judgment that Defendants have violated the APA by failing to notify the public and afford it an opportunity to comment on, at a minimum, the [Institutional Animal Committee] exemption of NIH Grants Policy Statement Sec. 4.1.1.4, the [Institutional Animal Committee] [e]xemption of the [Humane Care Policy], the [Institutional Animal Committee] exemption on the NIH Foreign Grants website, the [Institutional Animal Committee] exemption of the Foreign Animal Welfare Assurance Rules, and any equivalent agency rules, requirements, and publications;” and (5) “an order vacating and setting aside, at a minimum the [Institutional Animal Committee] exemption of NIH Grants Policy Statement Sec. 4.1.1.4, the [Institutional Animal Committee] [e]xemption of the [Humane Care Policy], the [Institutional Animal Committee] exemption on the NIH Foreign Grants website, the [Institutional Animal Committee] exemption of the Foreign Animal Welfare

Assurance Rules, and any equivalent agency rules, requirements, and publications unless and until the provisions have been properly adopted through notice-and-comment rulemaking.”

Finally, Plaintiff asks the Court to “award [Plaintiff] its costs and expenses, including reasonable attorneys’ fees pursuant to applicable statutes and/or rules” and to “grant further and additional relief as this Court may deem just and proper.” Am. Compl. at 32, ¶¶ D, E, F, G.

The Government now moves to dismiss under Rules 12(b)(1) and (6).

STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(1), a plaintiff bears the burden of proving that the Court has subject-matter jurisdiction to hear its claims. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *U.S. Ecology, Inc. v. Dep’t of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an “affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority.” *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). For this reason, “‘the [p]laintiff’s factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion’ than in resolving a 12(b)(6) motion for failure to state a claim.” *Id.* at 13-14 (quoting 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1350 (2d ed. 1987) (alteration in original)). Additionally, unlike when considering a motion to dismiss under Rule 12(b)(6), the Court “may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction.” *Jerome Stevens Pharms. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005); *see also Venetian Casino Resort, LLC v. EEOC*, 409 F.3d 359, 366 (D.C. Cir. 2005) (“[G]iven the present posture of this case—a dismissal under Rule 12(b)(1) on ripeness grounds—the court may consider materials outside the pleadings.”); *Herbert v. Nat’l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

The elements of Article III standing are “an indispensable part of the plaintiff’s case,” and “each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof.” *Lujan*, 504 U.S. at 561. At the pleading stage, a plaintiff’s factual allegations must be more than merely conclusory legal statements to the effect that standing exists or that the plaintiff was injured. As the Supreme Court has stated, “[i]t is the responsibility of the complainant clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute and the exercise of the court’s remedial powers.” *Warth v. Seldin*, 422 U.S. 490, 518 (1975); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (complaint’s statement of the grounds for relief requires “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do”); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions,” and a court need not accept as true “‘naked assertion[s]’ devoid of ‘further factual enhancement’”) (quoting *Twombly*, 550 U.S. at 557).

ARGUMENT

I. PLAINTIFF LACKS ARTICLE III STANDING

The Court should dismiss Plaintiff’s claim as White Coat lacks Article III standing. “To state a case or controversy under Article III, a plaintiff must establish standing.” *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133-34 (2011); *see Dominguez v. UAL Corp.*, 666 F.3d 1359, 1361 (D.C. Cir. 2012) (standing is a necessary “predicate to any exercise of our jurisdiction”). To establish standing generally, a plaintiff must demonstrate having suffered an injury-in-fact, specifically an injury that is “concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.” *Clapper v. Amnesty Int’l*, 568 U.S. 398, 409 (2013). *See Lujan*, 504 U.S. at 560-61.

A plaintiff must meet three requirements to establish standing. First, the plaintiff must have suffered an injury in fact, “an actual or imminent invasion of a legally protected, concrete and particularized interest.” *Ctr. for Law & Educ. v. Dep’t of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005) (citing *Lujan*, 504 U.S. at 560-61); *Nat’l Assoc. of Home Builders v. EPA*, 667 F.3d 6, 11 (D.C. Cir. 2011) (“The ‘irreducible constitutional minimum of standing contains three elements’: (1) injury-in-fact, (2) causation, and (3) redressability.”). Second, “there must be a causal connection between the alleged injury and the defendant’s conduct at issue.” *Id.* That is, the injury must be “‘fairly traceable to the challenged action.’” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Third, “it must be ‘likely,’ not ‘speculative,’ that the court can redress the injury.” *Ctr. for Law & Educ.*, 396 F.3d at 1157 (citing *Lujan*, 504 U.S. at 560-61).

An organization seeking to establish standing may “sue either on their own behalf (‘organizational standing’) or on behalf of their members (‘representational standing’).” *Citizens for Resp. & Ethics in Wash. (“CREW”) v. U.S. Off. of Special Counsel*, 480 F. Supp. 3d 118, 126-27 (D.D.C. 2020). It is not entirely clear from Plaintiff’s Amended Complaint whether White Coat seeks to establish representational standing in addition to organizational standing. *See generally* Am. Compl. One thing is clear—Plaintiff fails to allege facts sufficient to establish either.

A. Plaintiff Fails to Establish Organizational Standing

For organizational standing, an organization must allege a “concrete and demonstrable injury to [its] activities.” *CREW*, 480 F. Supp. 3d at 127. The organization cannot establish standing by seeking to “vindicate their own value preferences through the judicial process.” *Id.* The D.C. Circuit uses a two-part test to analyze this inquiry: the court asks first “whether the

agency's action or omission to act 'injured the [organization's] interest''; then, if satisfied, it inquires whether "the organization 'used its resources to counteract the harm.'" *PETA v. Dep't of Agric.* ("*PETA II*"), 797 F.3d 1087, 1094 (D.C. Cir. 2015); (alteration in original) (quoting *Equal Rts. Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1140 (D.C. Cir. 2011); accord *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015) (employing same test); see also *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (finding organizational injury based on an "injury to the organization's activities" followed by "the consequent drain on the organization's resources"). In reviewing the injury analysis, the government activity must "perceptively impair [] the organization's ability to provide services." *CREW*, 480 F.Supp. 3d at 127. It is not enough that the organization's mission has been compromised. *Id.* (citing *Abigail All. for Better Access to Dev. Drugs v. Eschenbach*, 469 F.3d 129, 133 (D.C. Cir. 2006)). And not all use of resources will meet the second part of the test. *CREW*, 480 F. Supp. 3d at 128. "[T]he devotion of resources to advocacy for the organization's preferred policy—whether that advocacy is directed at Congress, the courts, or an administrative agency—falls short of the line." *Id.* at 128 (citing, among others, *Ctr. for Responsible Sci. v. Gottlieb*, 346 F. Supp. 3d 29, 37 (D.D.C. 2018)). These are considered "self-inflicted" injuries. *Id.* (citing *Abigail All.*, 469 F.3d at 133).

Here, Plaintiff fails both prongs of the test. Nothing alleged in the Amended Complaint supports the conclusion that Defendants' actions have perceptively impaired the White Coat's ability to provide any services. See generally Am. Compl. Rather, White Coat expressly alleges that its mission is being compromised, see Am. Compl. ¶ 7 ("[White Coat] brings this action on its own behalf, and on behalf of its members, because the challenged conduct conflicts with, impairs, and frustrates its organizational mission"), which is insufficient under D.C. Circuit

precedents. *See Abigail All.*, 469 F.3d at 133. White Coat alleges that Defendants’ actions have “required it to divert and redirect its limited resources” and that this “hinders the development of other organizational projects that would better advance [White Coat’s] mission[.]” Am Compl.

¶ 7. White Coat fails to specify what resources that it has invested as a result of Defendants’ action and why it was required to invest such resources. Nor does White Coat articulate what alternative projects it was compelled to forego and why such decisions were compelled by Defendants’ actions. Plaintiff has thus failed to allege facts sufficient to meet either prong of the D.C. Circuit’s test to establish organizational standing.

B. Plaintiff Fails to Establish Representational Standing

Any attempt by Plaintiff to establish representational standing fares no better. “To have representational standing, an organization must show that ‘(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.’” *Friends of Animals v. Ashe*, 174 F. Supp. 3d 20, 28 (D.D.C. 2016) (citing *Home Builders*, 667 F.3d at 11 (quoting *Ass’n of Flight Attendants v. Dep’t of Transp.*, 564 F.3d 462, 464 (D.C. Cir. 2009), and *United Food & Com. Workers Union v. Brown Grp., Inc.*, 517 U.S. 544, 553 (1996))). To obtain injunctive relief in particular, as White Coat seeks to do, a plaintiff “must show under the first prong of the test that at least one of its members ‘is under threat of suffering injury in fact that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical’; it ‘must be fairly traceable to the challenged action of the defendant’[]—and “it must be likely that a favorable judicial decision will prevent or redress the injury.’” *Home Builders*, 667 F.3d at 12 (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 493, (2009) (quoting *Friends of Earth, Inc.*

v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 180–81 (2000))). While the burden of production to establish standing is more relaxed at the pleading stage than at summary judgment, a plaintiff must nonetheless allege “‘general factual allegations of injury resulting from the defendant's conduct.’” *Sierra Club v. EPA*, 292 F.3d 895, 898–99 (D.C. Cir. 2002) (quoting *Lujan*, 504 U.S. at 561 (alteration in *Sierra Club*)).

Again, Plaintiff fails to allege facts sufficient to meet several of the test’s prongs. First, Plaintiff fails to allege facts sufficient to demonstrate that its members would have standing to sue in their own right. *See generally* Am. Compl. White Coat has not carried its burden because it has neither sufficiently alleged nor persuasively demonstrated any threat of injury in fact to any of its members that is fairly traceable to an action of Defendants. On the causation prong, Plaintiff must demonstrate a connection between the alleged injury to the member and the agency action at issue. *Ctr. for Law & Educ.*, 396 F.3d at 1157 (citing *Lujan*, 504 U.S. at 560–61). Here, White Coat takes issue with the process NIH uses to approve animal welfare assurances for foreign institutions applying for research grants but never explains what injury this causes to its individual members aside from the inability to obtain unspecified information about foreign grant applicants. Second, Plaintiff fails to show that it seeks to protect interests that are “germane to the organization’s purpose.” In the Amended Complaint, White Coat asserts that the separate process for obtaining an animal welfare assurance as a foreign institution disadvantages domestic research institutions. *See* Am. Compl. ¶¶ 56, 74, 92, 110, 123, 143, 165, 183 (alleging that the NIH guidance at issue “allows foreign entities to compete for taxpayer funds at a discount, as compared to domestic entities”). But the White Coat does not claim to represent domestic research institutions and so its claimed interest in the way that NIH issues animal welfare assurances to domestic and foreign grant applicants is not germane to White

Coat's purpose. In sum, White Coat fails to meet multiple prongs of the test required to establish representational standing, and its claim should therefore be dismissed.

C. Plaintiff Fails to Establish Informational Standing

Plaintiff fails to plead informational standing because it does not identify what information it is entitled to by law or how the deprivation of this information results in a particularized injury in fact. Plaintiff alleges that NIH's foreign assurance guidance "excuses foreign grant recipients from maintaining records related to its animal care committee as well as reporting requirements involving violations that White Coat would otherwise be able to obtain through the Freedom of Information Act, had the recipient been a domestic entity." Plaintiff asserts that this alleged double standard caused it to suffer "a significant and irreparable informational injury that is actual and/or imminent." Am. Compl. ¶¶ 7, 194. These allegations cannot sustain an informational injury.

To establish an informational injury, a plaintiff must allege that "(1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure." *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) ("*Friends of Animals I*"). "It is not enough . . . to assert that disclosure is required by law. Only if the statute grants a plaintiff a concrete interest in the information sought will he be able to assert an injury in fact." *Nader v. Fed. Election Comm'n*, 725 F.3d 226, 229 (D.C. Cir. 2013); compare *Friends of Animals v. Jewell*, 824 F.3d 1033, 1041 (D.C. Cir. 2016) ("*Friends of Animals I*") (finding informational injury under Section 10(c) of the Endangered Species Act, which required that information received by the Secretary be made available to the public) with *Friends of Animals II*, 828 F.3d at 992-94 (finding no informational injury under

Section 4 of the ESA). As in *Friends of Animals II*, Plaintiff cannot assert that a general interest in legal compliance creates a right to particular information, and that the inability to access that information confers Article III standing.

The Supreme Court and this Court have found that a party has standing when Congress expressly creates an individual right to receive information and subsequent conduct infringes on the informational right. *Pub. Citizen v. FTC*, 869 F.2d 1541, 1548 (1989); *Zivotofsky v. Sec’y of State*, 444 F.3d 614, 617 (D.C. Cir. 2006). An invasion of an individual right to information is sufficiently concrete because it is “capable of judicial resolution” and is sufficiently particularized because it affects the plaintiffs in an individual way. *Zivotofsky*, 444 F.3d at 619. Thus, courts recognize a cognizable injury sufficient for standing only when the statutory provisions under which a plaintiff sues are intended by Congress to grant a right of information. *See Fed. Election Comm’n v. Akins*, 524 U.S. 11, 20-21 (1998) (holding that a plaintiff’s “inability to obtain information” that the Federal Election Campaign Act required to be made public created an injury in fact because the Act’s purpose was to protect voters by ensuring that they had relevant information that was required); *see also Pub. Citizen v. Dep’t of Just.*, 491 U.S. 440, 445-46, 449-50 (1989) (finding that denial of information subject to disclosure under the Federal Advisory Committee Act established standing because the purpose of the Act was to keep Congress and the public apprised of the existence, activities, and cost of advisory committees).

Here, Plaintiff has not alleged a concrete and particularized deprivation of information to which it is entitled by law. White Coat alleges that it has been unlawfully deprived of unspecified “pertinent information” about the animal care practices of foreign institutions with approved animal welfare assurances. Am. Compl. ¶¶ 57, 75, 93, 111, 124, 144, 164, 184.

Section 495 of the Services Act does not require that NIH make public any records it receives as part of grant applicants' requests for approval of animal welfare assurances. In fact, the Services Act does not even require grantees to report violations of animal care standards to NIH. Rather, the only provision of the Services Act that requires grantees' animal care committees to submit information about violations to NIH is 42 U.S.C. § 289d(b)(3)(c) and this allows grantees' animal care committees to file assurances that the grantee is complying with 42 U.S.C. § 289d(b)(1) in lieu of reporting each violation. Accordingly, while it is not clear what specific information White Coat believes it is entitled to, the Services Act does not confer on the public a right to receive any particular information about approved animal welfare assurances.

Indeed, this provision is distinguishable from the one that conferred an informational right in *Friends of Animals I*, 824 F.3d 1033. In that case, the court determined that Section 10(c) of the ESA created a right to information because Section 10(c), in pertinent part, provided: "Information received by the Secretary as a part of any application shall be available to the public as a matter of public record at every stage of the proceeding." 16 U.S.C. § 1539(c). Here, by contrast, the Services Act Section 495 does not confer any informational rights on the White Coat and does not require that NIH make public any information that it obtains as part of the process that NIH follows to approve animal welfare assurances. Even if White Coat could explain its legal entitlement to the "pertinent information" it seeks, it fails to articulate its particularized need for this information aside from a general interest in the use of animals in NIH funded research. Accordingly, Plaintiff fails to plead informational standing.

D. Plaintiff Lacks Procedural Standing to Bring its Alternative Claims for Relief

Contrary to Plaintiff's allegations, NIH has in fact offered the public the opportunity to submit comments on the Humane Care Policy. *See e.g.*, 67 Fed. Reg. 14,956. (Mar. 28, 2002). In

fact, the Humane Care Policy is among the policies listed in the Code of Federal Regulations as applying to NIH grant applicants. 22 C.F.R. § 52.8. Even assuming NIH never provided an opportunity for the public to submit comments on its application of the animal welfare assurance requirement to foreign grant applicants, White Coat lacks standing to bring its procedural claims under the APA. In *Summers v. Earth Island Institute*, 555 U.S. 488, 496 (2009), the Supreme Court stated that “deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.” *Id.* The requirement of an injury-in-fact is a “hard floor” for Article III standing. *Id.* at 497.

Because White Coat has failed to establish that the NIH guidance on foreign animal welfare assurances has caused or will imminently cause the organization or its members injury-in-fact, it therefore fails to establish any procedural standing to challenge Defendants’ promulgation of this guidance. *See Home Builders v. EPA*, 667 F.3d at 15 (“Without an imminent threat of injury traceable to the challenged action, that floor [i.e., the requirement of injury in fact] stands as a ceiling.”); *United Transp. Union v. Interstate Com. Comm’n*, 891 F.2d 908, 918 (D.C.Cir.1989) (“[B]efore we find standing in procedural injury cases, we must ensure that there is some connection between the alleged procedural injury and a substantive injury that would otherwise confer Article III standing. Without such a nexus, the procedural injury doctrine could swallow Article III standing requirements.”) As discussed above, Plaintiff fails to allege a specific, concrete injury that is traceable to NIH’s guidance to foreign research institutions on obtaining an animal welfare assurance. “A prospective plaintiff must demonstrate that the defendant caused the particularized injury, and *not just* the alleged procedural violation.” *Ctr. for Law & Educ.*, 396 F.3d at 1159 (internal quotation marks omitted; emphasis in original).

II. PLAINTIFF FAILS TO STATE A CLAIM UNDER THE ADMINISTRATIVE PROCEDURE ACT

Plaintiff fails to state an APA claim in this case because Section 495 of the Services Act does not protect Plaintiff's interest in acquiring more information about foreign recipients of NIH funding. In what used to be referred to as "prudential standing," a plaintiff cannot bring suit for violations of statutes that were never intended to promote the interests plaintiff's suit would advance, based on the presumption "that a statutory cause of action extends only to plaintiffs whose interests 'fall within the zone of interests protected by the law invoked.'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). To challenge agency action under the APA, a plaintiff must assert an interest that falls "arguably within the zone of interests protected or regulated by the statute." *Match-E-Be-Nash-She-Wish Band of Pottawatomis Indians v. Patchak*, 567 U.S. 209, 224 (2012) (quoting *Ass'n of Data Processing Serv. Orgs. Inc. v. Camp*, 397 U.S. 150, 153 (1970)). A zone of interests dismissal is made under Rule 12(b)(6). *See Maiden Creek Assocs. v. Dep't of Transp.*, 823 F.3d 184, 189 n.1 (3d Cir. 2016) ("[W]e must analyze . . . dismissal under Rule 12(b)(6) because the issue is whether appellants alleged harm that falls within NEPA's zone of interests, a question of statutory standing.").

Plaintiff's stated interest in NIH's guidance on animal welfare assurances for foreign grantees does not fall within the zone of interests protected by Section 495 of the Services Act. White Coat asserts that the foreign animal welfare assurance guidance prevents it from receiving the type of information that it receives about domestic grantees through requests under the Freedom of Information Act. "To come within the zone of interests of the statute under which suit is brought, an organization must show more than a general corporate purpose to promote the

interests to which the statute is addressed. *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 503 (D.C. Cir. 1994). Rather, it must show a congressional intent to benefit the organization or some indication that the organization is “a peculiarly suitable challenger of administrative neglect.” *Id.* (quoting *Akins*, 524 U.S. at 20). “Informational injury, without more, does not fall within the zone of interests of the statute under which suit is brought.” *Animal Legal Def. Fund*, 23 F.3d at 502. The D.C. Circuit has observed that “[i]f any person or organization interested in promoting knowledge, enjoyment, and protection of the rights created by a statute . . . has an interest that falls within the zone protected or regulated by the statute . . . then the zone-of-interests test is not a test because it excludes nothing.” *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 813 (D.C. Cir. 1987); *see also Animal Legal Def. Fund*, 23 F.3d at 502 (stating that “[a] continuous line of circuit precedent hold that claims of informational injury can surmount the zone of interests threshold only in very special statutory contexts”).

Services Act Section 495 provides for the establishment of laboratory animal care guidelines for institutions that receive NIH funds. It requires HHS to establish such guidelines and for the grant applicants to assure NIH of their compliance with those guidelines. Plaintiff does not allege that it applies for or receives NIH funds or submits animal welfare assurances for NIH approval. Rather, Plaintiff tersely asserts that the guidance at issue “reduces transparency” about the use of animals in government-funded research. *See Am. Compl.* ¶¶ 93, 111, 124, 144, 164, 184. The inability to disseminate more comprehensive information about the institutional oversight of the use of laboratory animals by NIH grantees is not an injury against which the Services Act protects and therefore it falls outside the zone of interests of the statute. Accordingly, Plaintiff fails to state an APA claim challenging NIH’s foreign animal welfare

assurance guidance based on its desire that NIH make more information about its grant recipients accessible to Plaintiff through the Freedom of Information Act.

CONCLUSION

Defendants present numerous justifications for the dismissal of the Complaint. In sum, dismissal is warranted under Rules 12(b)(1) and 12(b)(6) as Plaintiff lacks Article III standing and fails to state a claim.

Dated: September 20, 2022
Washington, D.C

Respectfully submitted,

MATTHEW M. GRAVES
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

By: /s/ Michael E. Yohannan
MICHAEL E. YOHANNAN
Pennsylvania Bar No. 307575
Special Assistant United States Attorney
U.S. Attorney's Office, Civil Division
601 D Street, N.W.
Washington, D.C. 20530
Tel: (202) 815-8969
Michael.Yohannan@usdoj.gov

Counsel for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITE COAT WASTE PROJECT, INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.,

Defendants.

Civil Action No. 22-0006 (CJN)

[PROPOSED] ORDER

Upon consideration of Defendants' Motion to Dismiss, Plaintiffs' opposition and any replies thereto, it is hereby

ORDERED that Defendants' motion is GRANTED; and it is further

ORDERED that the Complaint is DISMISSED.

SO ORDERED.

Dated

United States District Judge