UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DR. PIERO ANVERSA and, DR. ANNAROSA LERI,	
Plaintiffs,	
v.	
PARTNERS HEALTHCARE SYSTEM, INC., HARVARD MEDICAL SCHOOL, BRIGHAM AND WOMEN'S HOSPITAL, DR. ELIZABETH NABEL, and DEAN GRETCHEN BRODNICKI,	**Civil Action No. 14-14424-DJC**
Defendants.	

MEMORANDUM AND ORDER

CASPER, J. **July 27, 2015**

I. Introduction

Plaintiffs Drs. Piero Anversa ("Anversa") and Annarosa Leri ("Leri") (collectively, "Plaintiffs") have filed this lawsuit against Defendants Partners Healthcare System, Inc. ("Partners"), Harvard Medical School ("HMS"), Brigham and Women's Hospital (the "Brigham"), Dr. Elizabeth Nabel ("Nabel") and Dean Gretchen Brodnicki ("Brodnicki") (collectively, "Defendants") alleging breach of contract, breach of the implied covenant of good faith and fair dealing, tortious interference claims, and violations of Mass. Gen. L. c. 93A, § 11 and c. 214, § 1B. D. 1. Defendants have moved to dismiss all claims. D. 17, 19. For the reasons stated below, the Court ALLOWS the motions.

II. Standard of Review

A. Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)

In considering a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), the Court will dismiss a pleading that fails to plead "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007); see SEC v. Tambone, 597 F.3d 436, 442 (1st Cir. 2010) (noting that "[i]f the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal"). To state a plausible claim, it need not contain detailed factual allegations, but the claim must recite facts sufficient to at least "raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. at 555 (internal citation omitted). This determination requires a two-step inquiry. García-Catalán v. United States, 734 F.3d 100, 103 (1st Cir. 2013).

First, the Court must distinguish between the factual allegations and the conclusory legal allegations in the complaint. Id. Second, taking the plaintiff's allegations as true, the Court should be able to draw "the reasonable inference that the defendant is liable for the misconduct alleged." Id. (quoting Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir.2011)). However, "[i]n determining whether a complaint crosses the plausibility threshold, 'the reviewing court [must] draw on its judicial experience and common sense.' This context-specific inquiry does not demand 'a high degree of factual specificity.'" Id. (citations omitted).

B. Motion to Dismiss for Lack of Subject Matter Jurisdiction

"When considering a motion to dismiss under subsection 12(b)(1) of the Federal Rules of Civil Procedure, the Court should apply a standard of review 'similar to that accorded a dismissal for failure to state a claim' under subsection 12(b)(6)." Menge v. N. Am. Specialty Ins. Co., 905

F. Supp. 2d 414, 416 (D.R.I. 2012) (quoting Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995)); see Puerto Rico Tel. Co. v. Telecomm. Regulatory Bd. of Puerto Rico, 189 F.3d 1, 13 n.10 (1st Cir. 1999) (noting that "the standard of review . . . is the same for failure to state a claim and for lack of jurisdiction").

III. Factual Background

Unless otherwise noted, the facts are as alleged in the complaint, D. 1, and are taken as true for the purposes of this motion.

Anversa is a cardiovascular scientist. Id. ¶ 13. He is currently a Professor of Anesthesia and Medicine at HMS, the Director of the Center for Regenerative Medicine at the Brigham and the head of a laboratory at the Brigham (the "Brigham laboratory") focusing on myocardial regeneration and cardiac stem cells. Id. ¶¶ 14-16. Leri is a physician and researcher focusing on the molecular biology of cardiac stem cells. Id. ¶ 18. She is currently an Associate Professor of Anesthesia and Associate Professor of Medicine at HMS and a Principal Investigator in the Brigham laboratory. Id. ¶¶ 20-22.

A. Data Discrepancies in the 2012 Circulation Paper

In 2012, the Brigham laboratory published a paper in collaboration with the Lawrence Livermore National Laboratory ("LLNL"). Id. ¶ 23. Dr. Jan Kajstura ("Kajstura"), a senior scientist at the Brigham laboratory, is the first author of the paper, which was published in the journal Circulation in 2012 and reported 108 carbon-14 (C-14) measurements performed at the LLNL's Center for Accelerator Mass Spectrometry by Dr. Bruce Buchholz ("Buchholz"). Id. ¶ 24, 25. Kajstura was solely responsible for receiving the data from the LLNL and converting that data into figures and tables for the 2012 Circulation paper. Id. ¶ 26. Anversa drafted the 2012 Circulation paper based upon data provided to him by Kajstura and Leri supervised her

fellows in isolating DNA samples. Id. ¶¶ 31, 32. Neither Anversa nor Leri saw the raw data from LLNL prior to publication of the paper. Id. ¶ 30.

On October 16, 2012, after the paper was published, Buchholz contacted Anversa, Leri, and Kajstura regarding certain discrepancies in the data provided and the data reported in the paper. Id. ¶ 34. Buchholz indicated that he had only provided 88 C-14 measurements to Kajstura, not the 108 data points that had been reported. Id. ¶ 35. Prior to being contacted by Buchholz, Anversa and Leri were not aware of any problems with the data and were not fully aware of the problems with the data until sometime later. Id. ¶¶ 36, 42. On November 14, 2012, LLNL notified Brodnicki, HMS dean, about the data discrepancy. Id. ¶ 43.

B. Inquiry into Possible Research Misconduct

On January 10, 2013, Brodnicki informed Anversa and Leri that HMS and the Brigham would conduct a joint inquiry into three allegations of research misconduct. Id. ¶ 45. These initial allegations were that: (1) "Anversa and Leri falsified and/or fabricated the C-14 measurements in the 2012 Circulation paper by [] reporting 108 distinct data points when LLNL provided data for only 88 distinct measurements and [] reporting 8 data points with values inconsistent with the measurements provided by LLNL;" (2) "Anversa and Leri falsified and/or fabricated data in the 2012 Circulation paper by assigning isotope ratios to samples that have not been measured or reported by LLNL;" and (3) "Anversa and Leri 'falsified and/or fabricated data relating to the characterization of stem cells' and notes that '[q]uestions have arisen regarding the reproducibility of the phenotyping of cell populations." Id. ¶¶ 47, 48, 50. On March 8, 2013, Brodnicki informed Anversa and Leri that the inquiry would be expanded to include a fourth allegation, relating to Kajstura's apparent manipulation of confocal microscope images in an unpublished manuscript that had been submitted to the journals The Lancet and Science in 2013.

Id. ¶ 56. Drs. K. Frank Austen, Steven Gygi and Robert E. Kingston were the appointed members of the inquiry panel. Id. ¶ 59.

The inquiry was to be governed by HMS's Principles and Procedures for Dealing with Allegations of Faculty Misconduct (the "HMS bylaws"), Partners' Policy and Procedures for Handling Allegations of Research Misconduct (the "Partners bylaws"), and the Public Health Services Final Rule (the "PHS rule"), 42 C.F.R. § 93. Id. ¶ 46. Under the PHS rule, when allegations of research misconduct arise, an inquiry must first be conducted by the institution to determine whether an investigation is necessary. Id. ¶ 44 (citing 42 C.F.R. § 93.307). The PHS rule and the HMS and Partners bylaws require that the inquiry be completed within 60 days unless circumstances warranting a longer period are documented. Id. ¶ 60 (citing 42 C.F.R. § 93.307(g)). In this case, however, the inquiry panel did not meet the 60-day deadline, issuing the final inquiry report on February 28, 2014, more than a year after Anversa and Leri were notified of the inquiry. Id. ¶¶ 61, 67. The delay was exacerbated because the inquiry panel met only once a month and then took over two months to write draft reports and recommendations, even though Anversa and Leri's attorneys notified the panel on two occasions that the delay was causing unjustified damage to their professional reputations. Id. ¶¶ 62-65.

Ultimately, the inquiry panel recommended: (1) that the Lancet paper and the 2012 Circulation paper be retracted; (2) that the inquiry should proceed to an investigation; and (3) that there should be an evaluation of whether the Bingham laboratory was an appropriate environment for trainees. Id. ¶ 68. Although the inquiry panel found substantial evidence that Kajstura may have committed research misconduct acting alone, the panel nevertheless recommended that the inquiry proceed to an investigation against Anversa and Leri on the theory that they negligently failed to investigate Kajstura's misconduct. Id. ¶¶ 70, 72. Anversa and

Leri allege that the inquiry panel's reports were riddled with legal and factual errors. Id. ¶¶ 73, 75. On February 28, 2014, Anversa and Leri were notified that HMS and the Brigham would proceed with an investigation. Id. ¶ 76.

C. Investigation Panel's Alleged Defects

Plaintiffs allege that HMS, the Brigham and Partners have not ensured that the investigation is being conducted in compliance with federal law, the HMS bylaws and Partners bylaws. Id. ¶ 77 (citing 42 C.F.R. § 93.301).

1. Conflicts of Interest

Initially, HMS and the Brigham appointed the members of the inquiry panel – Drs. Austen, Gygi and Kingston – as the sole members of the investigatory panel. Id. ¶ 82. Plaintiffs allege that the composition of the investigatory panel violates the HMS bylaws, which require that the investigation be conducted by the Harvard Committee on Faculty Conduct and that Austen, Gygi and Kingston are not experts in the relevant scientific areas, as required by the PHS rule. Id. ¶¶ 77-80, 83. Moreover, Plaintiffs allege that Austen, Gygi and Kingston cannot in good faith conduct a fair and impartial investigation, as required by the PHS rule, of allegations recommended by an inquiry report they authored. Id. ¶¶ 84-86.

On April 3, 2014, Dr. Ulrich von Andrian was added to the investigatory panel. Id. ¶ 87. Von Andrian is a member of the Scientific Advisory Board of Moderna Therapeutics, Inc. ("Moderna"), which is pursuing an alternative therapy of regenerative treatment of cardiac disease and, therefore, competes with the Brigham laboratory for clinical trial opportunities, funding and commercial development. Id. ¶ 89-91. In the past, members of the Moderna Scientific Advisory Board have criticized the c-kit positive human cardiac stem cell model that is

espoused by Anversa and Leri and had also intervened to delay Anversa's appointment to the Harvard faculty. Id. ¶¶ 92, 94-95.

On September 15, 2014, Gygi resigned from the investigatory panel after concerns were raised by Anversa and Leri regarding conversations Gygi had with scientific collaborators about the ongoing investigation. Id. ¶ 103. In his resignation, Gygi acknowledged the perception of bias caused by his participation on the investigatory panel. Id.

2. Undue Delay

The PHS rule, the HMS bylaws and Partners bylaws require that the investigation be completed within one hundred and twenty days unless HMS and the Brigham request and obtain, in writing, an extension from the Office of Research Integrity ("ORI") at the United States Department of Health and Human Services. Id. ¶ 109 (citing 42 C.F.R. § 93.311(a)-(b)). As alleged by the Plaintiffs, the investigation, therefore, should have been completed by June 28, 2014. Id. ¶ 110. On May 15, 2014 and October 2, 2014, however, the investigatory panel issued additional allegations that had not been before the inquiry panel and that concerned additional papers. Id. ¶¶ 105, 107. Although the investigatory panel did not obtain an official extension before the deadline expired, id. ¶ 111, ORI subsequently granted two extensions to accommodate additional allegations and to pursue all issues. D. 18 at 11 & n.2. The most recent deadline was June 30, 2015. Id. at 11 n.2. Since all of the papers cited in the new allegations were published before the investigation began in February 2014, however, Plaintiffs allege that "[t]here is no justification for expanding the investigation to encompass these additional papers at this late stage." D. 1 ¶ 108.

3. Breaches of Confidentiality

Plaintiffs also allege that Defendants have disclosed confidential information in violation of the PHS rule, the HMS bylaws and Partners bylaws. Id. ¶ 113. Under the PHS rule, the disclosure of the identity of respondents in a research misconduct investigation is limited "to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law." D. 25 at 11 (quoting 42 C.F.R. § 93.108(a)). In this case, however, members of the scientific community and the media, who did not need to know, learned about the inquiry and the investigation due to the disclosures of Defendants. See, e.g., D. 1 ¶¶ 116-119; 120-126; 129-136. For example, on March 25, 2014, Dean Brodnicki notified journals The Lancet and Circulation of the ongoing investigation and recommended retracting certain papers. Id. ¶ 120. Brodnicki's notification was contrary to established practices since it is customary to explore issuing a correction before any retraction. Id. ¶ 122. After receiving Brodnicki's notification, Circulation issued a retraction and The Lancet issued an expression of concern. Id. ¶¶ 125, 126. The journals' actions were widely reported in the media and Anversa was specifically identified as a co-author of the papers. Id. ¶¶ 129, 130. In contrast, Kajstura was not identified in any media reports as the individual accused of actually falsifying or fabricating data. Id. ¶ 132.

Defendant Nabel also disclosed information regarding the investigation. Id. ¶ 137. Nabel encouraged Circulation's editor-in-chief to retract the paper and implied to him that Anversa and Leri had personally committed research misconduct. Id. ¶¶ 138, 140. Nabel also disclosed information about the investigation to members of the Brigham laboratory, implying that there was a problem with the mentorship provided by Anversa and Leri. Id. ¶¶ 143, 147.

Finally, Gygi, who previously served on the inquiry and investigatory panels, discussed the investigation with a colleague at Duke University, telling him that the panel was "going after all [Plaintiffs'] work" and that more papers would be retracted. Id. ¶¶ 149, 150. As noted above, Gygi subsequently resigned his position and acknowledged that he had disclosed that he was serving on a research misconduct panel. Id. ¶¶ 152, 153.

As a result of the inquiry and investigation process, Plaintiffs allege that their reputations have been damaged; they lost a multimillion-dollar offer to purchase their company, Autologous/Progenital; and both Plaintiffs have had possible employment offers at several institutions postponed. Id. ¶¶ 156-59.

IV. Procedural History

Plaintiffs instituted this action on December 16, 2014 seeking damages and declaratory relief. D. 1. Defendants subsequently moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).[1] D. 17, 19. The Court heard the parties on the pending motions on June 10, 2015 and took these matters under advisement. D. 35.

V. Discussion

A. Administrative Exhaustion

All Defendants argue that Plaintiffs have failed to exhaust administrative remedies. D. 18 at 18; D. 20 at 17. Specifically, Defendants argue that the Court lacks jurisdiction under both the statutory and common law principles of administrative exhaustion.

1. Statutory Scheme Precludes Pre-enforcement Jurisdiction

[1] As a threshold matter, the Court must address Defendants' jurisdictional arguments. See, e.g., O'Connell Mgmt. Co. v. Massachusetts Port Auth., 744 F. Supp. 368, 371 (D. Mass. 1990) (noting "that subject matter jurisdiction is a threshold requirement which must be satisfied before a decision on the substantive merits presented by a 12(b)(6) motion can be considered").

Defendants HMS and Brodnicki argue that judicial intervention is premature because the applicable statutory scheme precludes judicial review at this stage. D. 20 at 14-15. Specifically, Defendants argue that the "statutory scheme requires Plaintiffs' claims to undergo a detailed process of administrative review" before judicial review can be triggered. Id. at 15. The question for the Court is whether the administrative structure of the Public Health and Welfare Act (the "Act") was intended to preclude the district court's jurisdiction of Plaintiffs' claims and whether those claims can be meaningfully reviewed through the administrative structure consistent with due process. See Thunder Basin Coal Co. v. Reich, 510 U.S. 200, 207 (1994) (holding that "[w]hether a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, and whether the claims can be afforded meaningful review") (internal citation omitted).

a) The Statutory Scheme

Pursuant to the Act, the Secretary of the United States Department of Health and Human Services ("HHS") established the Office of Research Integrity ("ORI") to investigate all reports of research misconduct from institutions receiving HHS funding. See 42 U.S.C. § 289b.[2] The regulations require institutions to establish proceedings to investigate good-faith allegations of research misconduct and then report the results to the ORI, which in turn reviews the case and makes an independent determination as to whether misconduct occurred. 42 C.F.R. §§ 93.203, 403-404 (2009). "Research misconduct" is defined as the:

> fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

[2] The relevant section of 42 U.S.C. § 289b reads in part: "The Secretary shall by regulation require that each entity that applies for financial assistance under this [Act] . . . submit . . . assurances . . . that such entity has established and has in effect . . . an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity . . . ." Id. § 289b(b)(1).

> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

Id. § 93.103. Given the serious nature of these proceedings, the regulations impose confidentiality obligations on research misconduct proceedings, providing that:

> Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:
>
> > (1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under § 93.403.
> >
> > (2) Under § 93.517(g), HHS administrative hearings must be open to the public.

Id. § 93.108(a). With regard to the investigation proceedings that must be established by institutions receiving federal funding for research, the regulations mandate that the institutions must establish a two-tiered procedure for responding to good-faith allegations of research misconduct: (1) an inquiry and (2) an investigation. Id. §§ 93.212, 307-309 (inquiry); 93.215, 310-313 (investigation).

"The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation." Id. § 93.307(c). An investigation should be considered warranted if there is "(1) [a] reasonable basis for concluding that the allegation falls within the

definition of research misconduct . . . and (2) [p]reliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance." Id. § 93.307(d). The institution must complete its inquiry "within 60 calendar days of its initiation unless circumstances clearly warrant a longer period." Id. § 93.307(g). At the conclusion of the inquiry, the institution must complete a written report of the inquiry panel's decision and, if the panel has determined that the allegations warrant an investigation, send the report to the ORI. Id. §§ 93.307(e), 309(a).

The investigation, if necessary, is "the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct . . . ." Id. § 93.215. The investigation must be commenced within thirty days of a determination that an investigation is warranted and notice must be sent to the respondent before the investigation begins. Id. § 93.310(a), (c). Institutions must ensure a fair investigation, "tak[ing] reasonable steps to ensure an impartial and unbiased investigation" while interviewing all relevant witnesses and diligently pursuing all leads. Id. § 93.310(f)-(h). As with the inquiry, the final determination of the investigation panel must be memorialized in a written report, which must be given to the respondent for comment and must be sent to the ORI. Id. §§ 93.312, 313, 315. While all aspects of the investigation must be completed within 120 days, if the institution is unable to complete the investigation by the deadline it can request an extension from ORI. Id. § 93.311(a)-(b). Any extension request must be in writing. Id. § 93.311(b).

Once the institution's investigation is complete, the ORI may conduct a review and request clarification or additional information or may propose administrative actions. Id. § 93.400(a)-(c). The ORI must obtain HHS approval for "administrative actions." Id.

§ 93.404(a). If the ORI concludes that a researcher committed misconduct, it notifies the researcher by sending him a "charge letter" describing the misconduct found and the sanctions proposed. Id. § 93.405(a). Possible HHS administrative actions include: (1) clarification, correction or retraction of the research record; (2) letters of reprimand; (3) imposition of special certification requirements; (4) suspension or termination of a PHS grant or contract; (5) restriction on specific activities or expenditures under an active PHS grant; (6) imposition of supervision requirements on a PHS grant or contract; (7) adverse personnel action if the respondent is a federal employee; and (8) suspension or debarment from future grant funding. Id. § 93.407(a).

A respondent "may contest ORI findings of research misconduct and HHS administrative actions, including any debarment or suspension action, by requesting a hearing [before an administrative law judge] within 30 days of receipt of the charge letter . . . ." Id. § 93.501(a). The respondent and the ORI are considered the only parties to any such hearing; the investigating institution is not considered a party to the case. Id. § 93.505(a). Parties to the hearing may: (1) be represented by counsel; (2) conduct discovery; (3) file motions in writing, including documents under seal; and (4) present evidence and cross examine witnesses at the hearing. Id. § 93.505(b). After the hearing, the ALJ issues a ruling in writing, which constitutes a recommended decision to the Assistant Secretary for Health, and the Assistant Secretary for Health then makes a final decision. Id. § 93.523(a)-(b). The Assistant Secretary for Health's decision is considered the final HHS action, unless debarment or suspension is recommended, in which case the Assistant Secretary of Health must serve a copy of that decision upon the HHS debarring official, who then makes the final HHS decision on the debarment or suspension. Id. § 93.523(b)-(c).

b) 42 U.S.C. § 289b Precludes Judicial Review at this Time

Plaintiffs argue that the statutory scheme does not preclude judicial review now because neither the statute nor the PHS rule explicitly foreclose jurisdiction and "Defendants identify no statute or regulation conferring exclusive jurisdiction in this matter on the ORI or HHS." D. 25 at 21-22. To determine whether a statute is intended to preclude initial judicial review, however, the question is whether Congress's intent to allocate initial review to the administrative body is "fairly discernible in the statutory scheme." Thunder Basin, 510 U.S. at 207 (quoting Block v. Community Nutrition Inst., 467 U.S. 340, 351 (1984)) (internal quotation marks omitted). As noted above, Courts must consider "the statute's language, structure, and purpose, its legislative history, and whether the claims can be afforded meaningful review." Id. (internal citation omitted). "If a statute does indeed route the initial adjudication of a claim through an administrative agency, a district court is without jurisdiction to hear the claim until administrative review is complete." McHugh v. Rubin, 220 F.3d 53, 59 (2d Cir. 2000) (citing Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000) and Thunder Basin, 510 U.S. at 202, 207, 218).

Here, although the Act is silent regarding pre-enforcement jurisdiction, it mandates a comprehensive structure for reviewing allegations of research misconduct. The enabling statute explicitly requires HHS to establish "a process" for conducting research misconduct investigations, 42 U.S.C. § 289b(c), and tasks ORI with "monitor[ing these] administrative processes and investigations . . . ." Id. § 289b(d). Under this statutory authority, HHS promulgated a regulatory scheme that provides a detailed process for administrative review of research misconduct. As discussed above, the regulations mandate that institutions must establish a two-tiered procedure for responding to good-faith allegations of research misconduct

and provide for ongoing review of institution proceedings by the ORI. See, e.g., id. §§ 93.212, 307-309 (inquiry); 93.215, 310-313 (investigation). Respondents may contest ORI findings and HHS administrative actions at a hearing before an administrative law judge, who provides a written decision to the Assistant Secretary for Health for final decision, with possibility of additional review by a debarring official. Id. §§ 93.501(a), 523(a)-(c). Thus, the Act's comprehensive enforcement structure establishes a "fairly discernible" intent to preclude district court review at the present time. See Thunder Basin, 510 U.S. at 207 (citation omitted) (internal quotation marks omitted).

Indeed, in Fals-Stewart v. Connors, Docket No. 49, No. 07-CV-00225E (W.D.N.Y. Aug. 24, 2007), a decision relied upon by Defendants, the court noted that the HHS regulations governing research misconduct preclude judicial review until the administrative review is complete. D. 21-2 at 10. In that case, a research scientist sought a preliminary injunction to enjoin a university from conducting an investigation into his alleged misconduct under the same statutory scheme at issue here. Id. at 5. Denying the preliminary injunction,[3] the Fals-Stewart court noted that:

> [w]hile plaintiff's allegations that the University Panel has failed to sequester documents and maintain confidentiality, if true, might establish that the University's Investigatory Panel has failed to fully comply with ORI regulations governing investigations, the remedy for such a violation is not an injunction from this Court. In fact, where, as here, a statute routes the initial adjudication of a claim through an administrative agency, a district court is without jurisdiction to hear the claim until administrative review is complete.

Id. at 10 (internal citation and quotation marks omitted) (quoting McHugh, 220 F.3d at 59). Similarly, the institutional investigation in this case is not yet complete and there has been no

[3] The parties in Fals-Stewart stipulated to dismissal prior to the court's ruling on a pending motion to dismiss. Fals-Stewart, No. 07-00225, Order, Stipulation of Dismissal with Prejudice, D. 100.

final administrative decision. As in Fals-Stewart then, if Anversa and Leri are "not satisfied with the outcome of the University's investigation, [they] ha[ve] multiple opportunities to raise [] procedural concerns throughout the administrative process . . . and if an adverse finding is forwarded to ORI, [they] can raise these arguments with ORI and to the ALJ, and if still unsatisfied, to a court on judicial review after the administrative process is complete." Id. Nothing in the Act suggests that Congress intended to allow respondents to enjoin the administrative misconduct review process by instituting a pre-enforcement challenge, as Plaintiffs are attempting to do here.

Accordingly, the Court concludes that the statutory scheme at issue here precludes this Court's jurisdiction at this time.

2. Common Law Doctrine of Administrative Exhaustion

Even if exhaustion is not statutorily mandated, judicial review is precluded under common law principles of administrative exhaustion.[4] "The doctrine of exhaustion of administrative remedies is well established in the jurisprudence of administrative law." McKart v. United States, 395 U.S. 185, 193 (1969). "The doctrine provides 'that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has

[4] Even where exhaustion is not statutorily mandated, application of the exhaustion doctrine is within the discretion of the court. See Accion Soc. de Puerto Rico, Inc. v. Viera Perez, 831 F.2d 365, 369 (1st Cir. 1987) (noting that "that exhaustion 'promotes a sensible division of tasks between the agency and the court: litigants are discouraged from weakening the position of the agency by flouting its processes, while court resources are reserved for dealing primarily with those matters which could not be resolved administratively'") (citation omitted)); see also McCarthy, 503 U.S. at 144 (noting that "[t]he doctrine of exhaustion of administrative remedies is one among related doctrines—including abstention, finality, and ripeness—that govern the timing of federal-court decisionmaking" and that "of 'paramount importance' to any exhaustion inquiry is congressional intent . . [b]ut where Congress has not clearly required exhaustion, sound judicial discretion governs") (citations omitted).

been exhausted.'" Id. (quoting Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51 (1938)). "Exhaustion is required because it serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency." McCarthy v. Madigan, 503 U.S. 140, 145 (1992), superseded by statute on other grounds, 42 U.S.C. § 1997e(a). Since the administrative agency is a separate entity invested with unique powers and duties, "courts ordinarily should not interfere with an agency until it has completed its action, or else has clearly exceeded its jurisdiction." McKart, 395 U.S. at 194. This is especially true "where the function of the agency and the particular decision sought to be reviewed involve exercise of discretionary powers granted the agency by Congress, or require application of special expertise." Id. The doctrine promotes judicial efficiency by encouraging a process that may well resolve the controversy. Id.; see P. Gioioso & Sons, Inc. v. OSHRC, 115 F.3d 100, 104 (1st Cir. 1997) (noting that "exhaustion of administrative remedies is generally required" as "exhaustion forces parties to take administrative proceedings seriously, allows administrative agencies an opportunity to correct their own errors, and potentially avoids the need for judicial involvement altogether") (citations and internal quotation marks omitted).

Here, Defendants argue that despite the varied remedies available, Anversa and Leri "have lodged no complaints with ORI, have not requested compliance actions from HHS, and have sought no relief from the ALJ." D. 18 at 19. In response, Plaintiffs argue that the common law exhaustion doctrine does not apply because the administrative process will not provide them with the full relief they seek since "[a]mong other relief, Plaintiffs seek monetary damages . . . [and] ORI and HHS have no authority to award Plaintiffs [sic] damages," D. 25 at 23-24, and because it would be futile to pursue remedies through the administrative process as "there are effectively no reasonable time limits on agency action . . . ." Id. at 24.

To determine whether exhaustion is required, "federal courts must balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." McCarthy, 503 U.S. at 146. "Application of this balancing principle is intensely practical because attention is directed to both the nature of the claim presented and the characteristics of the particular administrative procedure provided." Id. (internal citation and quotation marks omitted). The Supreme Court has identified "three broad sets of circumstances in which the interests of the individual weigh heavily against requiring administrative exhaustion." Id. "First, a court may consider relaxing the rule when unreasonable or indefinite delay threatens unduly to prejudice the subsequent bringing of a judicial action." Portela-Gonzalez v. Sec'y of the Navy, 109 F.3d 74, 77 (1st Cir. 1997). Second, "it sometimes may be inappropriate for a court to require exhaustion if a substantial doubt exists about whether the agency is empowered to grant meaningful redress." Id. And finally, "the exhaustion rule may be relaxed where there are clear, objectively verifiable indicia of administrative taint." Id. Plaintiffs' arguments implicate the first two circumstances.

With regard to Plaintiffs' first argument, although Plaintiffs do seek money damages here (as well as declaratory relief), the First Circuit has noted that "[e]xhaustion is beneficial regardless of whether the administrative process offers the specific form of remediation sought by a particular plaintiff." Frazier v. Fairhaven Sch. Comm., 276 F.3d 52, 61 (1st Cir. 2002). "After all, the administrative process facilitates the compilation of a fully developed record by a factfinder . . . and that record is an invaluable resource for a state or federal court required to adjudicate a subsequent civil action covering the same terrain." Id. Moreover, as a practical matter, permitting Plaintiffs to avoid the administrative process simply by requesting monetary damages or other relief outside of the ORI and HHS's authority would effectively do away with

an exhaustion requirement all together, allowing "the exception [to] swallow the rule." Frazier v. Fairhaven Sch. Comm., 122 F. Supp. 2d 104, 109 (D. Mass. 2000), aff'd, 276 F.3d 52 (1st Cir. 2002) (collecting cases concluding that plaintiffs should not be allowed to avoid administrative requirements simply by asking for relief that administrative authorities cannot provide).[5] As noted above, the Act established a comprehensive administrative review procedure to safeguard respondent's rights while a careful and thorough investigation is being conducted. In short, the Act provides administrative remedies for precisely the types of claims asserted by Plaintiffs. As such, the doctrine of administrative exhaustion is appropriately applied here to prevent circumvention of agency procedures. See Swirsky v. Nat'l Ass'n of Sec. Dealers, 124 F.3d 59, 62 (1st Cir. 1997).

As to Plaintiffs' futility argument, Plaintiffs' claims "must be anchored in demonstrable reality . . . [and] [a] pessimistic prediction or a hunch that further administrative proceedings will prove unproductive is not enough to sidetrack the exhaustion rule." Portela-Gonzalez, 109 F.3d at 78. Plaintiffs argue that seeking relief through the administrative process would be "futile" because "there are effectively no reasonable time limits on agency action"; "[t]here is no reason to believe that ORI will ever issue [] a finding here"; and "[t]he investigation has essentially been relegated to a black hole from which it may not emerge." D. 25 at 24-25 (citations and internal quotation marks omitted). As discussed above, however, the applicable regulatory framework

[5] Plaintiffs rely on Hettinga v. United States, 560 F.3d 498 (D.C. Cir. 2009), for the proposition that there is no exhaustion requirement when an agency lacks the power to award the relief sought. In that case, however, the court concluded that "[r]equiring exhaustion . . . would neither 'protect[ ] administrative agency authority' nor 'promot[e] judicial efficiency,'" because (1) administrative agencies generally do not have jurisdiction over constitutional challenges, and (2) additional administrative proceedings would provide no practical benefit to the court. Id. at 506 (citation omitted) (alternations in original). Here, in contrast, ORI has the authority to review the alleged deficiencies in the inquiry and investigation and further administrative review would provide a fuller record for review.

does set explicit time limits and permits ORI to exercise its discretion, based on its expertise, to grant extensions. See 42 C.F.R. §§ 93.307(g) (60 days to complete inquiry "unless circumstances clearly warrant a longer period"), § 93.311(a)-(b) (120 days to complete an investigation, with the opportunity to request extensions when necessary). Given the apparent scope of this investigation, the Court cannot conclude that the granting of two extensions by ORI is unreasonable or amounts to an indefinite delay. Moreover, the regulatory scheme is designed to provide respondents administrative review for the type of complaints raised, and although Plaintiffs have argued vigorously that they are being harmed by the investigation, it is unclear that they will suffer any substantial harm by being required to raise these issues in the first instance through the available administrative review structure.

Accordingly, the Court concludes that it lacks jurisdiction under both the statutory and common law principles of administrative exhaustion.

B. Defendants' Remaining Arguments for Dismissal

Defendants further argue that: (1) Defendants have immunity because all of Plaintiffs' claims are grounded in challenging the manner in which HMS and the Brigham have exercised a delegated discretionary government function, D. 18 at 12-15; (2) Plaintiffs' claims are preempted by federal law, id. at 16-18; and (3) Plaintiffs' claims should be dismissed because each count fails to state a claim upon which relief may be granted. Id. at 20-25; D. 20 at 19-29. In light of the Court's conclusions as to administrative exhaustion, however, the Court need not reach Defendants' remaining arguments.

VI. Conclusion

For the foregoing reasons, the Court ALLOWS Defendants' motions to dismiss, D. 17, 19. Given the grounds on which the Court allows these motions, the case is DISMISSED WITHOUT PREJUDICE.

So Ordered.

/s/ Denise J. Casper
United States District Judge