IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

IDIL ISSAK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 3:25-cv-238**
	)	
RANDY BOYD, PRESIDENT OF THE	)	
UNIVERSITY OF TENNESSEE	)	**Judge Crytzer**
SYSTEM, in his Official Capacity, *et al.*,	)	**Magistrate Judge McCook**
	)	
Defendants.	)	

REPLY IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

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In Issak's response (at Dkt. 53), she raises a First Amendment theory so vast that it is hard to imagine a requirement involving the use of language that would not require strict scrutiny. Here, since the challenged IRB-review requirement does not target speech but the risks and purpose of a contemplated research project, the most deferential standard of scrutiny is appropriate. This is doubly true in the context of this lawsuit: Issak is trying to act in the name of a university without giving it the chance to review her planned actions. That cannot be permitted.[1] Despite Issak's arguments, the Court still lacks subject matter jurisdiction, and the Amended Complaint still fails to state a claim.

I. This Court Lacks Jurisdiction.

Sovereign Immunity of IRB. The four-factor arm-of-the-State test demonstrates that the IRB is a component of UT and, thus, a state entity. Dkt. 41 at 11-14. Issak's arguments are unpersuasive. On the first factor—UT's liability for a judgment against the IRB—she offers no counterpoint, only speculating (at 7) that discovery might help. But a "plaintiff is not entitled to [jurisdictional] discovery if she cannot, at a minimum, 'offer any factual basis for [her] allegations' and give the district court 'a reasonable basis to expect that . . . discovery would reveal' evidence" of jurisdiction. C.*H. By & Through Shields v. United States*, 818 F. App'x 481, 484 (6th Cir. 2020) (citation omitted). Issak claims discovery would clarify the meaning of "state-funded" and "subsidiary." But so would a dictionary. She wants to probe how UT is funded. But that is irrelevant since *all* UT funds, "regardless of their source," are funds of the State. *Rives v. University of Tennessee*, No. 24-5336, 2024 WL 5103829, at *3 (6th Cir. Dec. 13, 2024). She wants to explore if UT ever refused to pay a judgment against the IRB. But she offers no reasonable basis to expect that discovery would reveal this. C.*H.*, 818 F. App'x at 484. Further, by filing a response, Issak abandoned the proper procedure of moving for jurisdictional discovery *before* responding. *Id.* at 483, 485-86. Thus, this factor still weighs firmly in IRB's favor.

[1] Defendants reject Issak's insinuation (at 9) that, in giving a history of the IRB, they compared her to a Nazi. At every step of this process, Defendants have striven to treat Issak with respect.

The remaining factors favor the IRB too. On the second—how state law and courts refer to the IRB—Issak overlooks that, because these sources refer to the IRB's creator, UT, as a state entity, the IRB need not be separately mentioned. Dkt. 41 at 12. While hammering the IRB's independence (at 8), she ignores Defendants' cited cases stating that sub-entities of a state agency can have autonomy while remaining "a part of the government of the state." Dkt. 41 at 13. She (at 8-9) properly concedes the third factor. On the fourth factor—the IRB's governmental role—she (at 9 n.8) does not rebut that the IRB furthers higher education. Dkt. 41 at 13. She instead (at 9) clings to the idea that immunity cannot apply since non-government entities also satisfy federal funding requirements. But this is no answer to *Medina*. And even *non-state* universities satisfying federal funding conditions can be protected by immunity. *See Kumar v. George Washington Univ.*, 174 F. Supp. 3d 172, 177-79 (D.D.C. 2016).

Standing and Cultural-Appropriateness. Issak's complaint challenges the IRB's requirement that she "obtain a letter" of cultural appropriateness as a viewpoint-based regulation. Dkt. 34 ¶¶ 172, 177. But Issak *already* obtained this letter, so she has no prospective injury. Dkt. 41 at 15. In nevertheless claiming ongoing injury, Issak (at 3-4) points to the requirement that her research comply with international and federal regulations. But that is not the injury she alleged, and she cannot amend her complaint through a response. *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 467 (6th Cir. 2014).

Standing and Narrowing of Research. Issak, not Defendants, caused the narrowing of her research. Dkt. 41 at 15-16. She claims (at 4-5) that the intertwined IRB and UT review proceedings from 2024 to 2025 caused "her most recent application" to contain "only 25% of the content she originally intended to research." As support, she cites her July 1, 2025 application. Dkt. 34 ¶ 114. But over a year earlier—in May 17, 2024—Issak reported that she was already "only doing 25 percent" of what she wanted. Dkt. 41-5 at 5. The subsequent IRB process, thus, did not cause the narrowing.

II. Issak fails to state a claim upon which relief can be granted.

Issak fails to state a claim because her case is barred by the statute of limitations, she lacks a

cause of action to sue the IRB, her claims are barred by qualified immunity, she fails to allege a First Amendment violation, and she does not show IRB review is an unconstitutional condition.

At the outset, Issak says (at 10-11) that the Court cannot consider the exhibits attached to the Motion to Dismiss. Not so. Issak relies on *Diei v. Boyd*, 116 F.4th 637, 644 (6th Cir. 2024), but *Diei* disproves her argument. It affirms that, at the Rule 12(b)(6) stage, courts may consider *all three* categories of Defendants' exhibits: documents referenced in and central to the Complaint, Dkts 41-3, 41-4, 41-5, 41-6; public records, Dkts. 41-1, 41-2, 41-3; and materials appropriate for judicial notice because they are not subject to reasonable dispute, Dkts. 41-1, 41-2, 41-3. *See Diei*, 116 F.4th at 643. *Diei* rejected only certain exhibits because their availability and relevance was disputed. *Id.* at 643-44. Issak does not suggest this of Defendants' exhibits. So, the Court may consider the exhibits as other courts have considered these or similar documents. *See, e.g.*, *City & Cnty. of San Francisco v. Garland*, 42 F.4th 1078, 1084 n.3 (9th Cir. 2022); *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 182 n.13 (2d Cir. 2009).

Statute of Limitations. The statute of limitations bars Issak's claims. Dkt. 41 at 17-19. In arguing (at 11-14) for application of the continuing-violation doctrine, Issak has no answer to the fact that the Sixth Circuit "rarely extends" it "to § 1983 actions." Dkt. 41 at 18 (citation omitted). She also fails to recognize that the ongoing IRB review process does not result from an amorphous hostile-work-environment-like harm, but is instead the consequence of the discrete, initial determination that her research must go through IRB review. *Kovacic v. Cuyahoga Cnty. Dep't of Child. & Fam. Servs.*, 606 F.3d 301, 308 (6th Cir. 2010). This determination is similar to other discrete acts with ongoing effects like the ongoing absence of children from a home after their unlawful removal from their parents, *Id.*; ongoing deductions from an inmate's account after initial application of a prison policy, *Montanez v. Sec'y Pennsylvania Dep't of Corr.*, 773 F.3d 472, 481 (3d Cir. 2014); or continual penalties after an initial citation for a zoning violation, *Miller v. King George Cnty.*, 277 F. App'x 297, 299-300 (4th Cir. 2008).

Cause of Action to Sue IRB. Even setting aside sovereign immunity, Issak lacks a cause of

action to sue the IRB. Dkt. 41 at 19. Issak's response, relegated to n.9, cites a case proving this point.

Qualified Immunity. Qualified immunity bars Issak's damages claims. Dkt. 41 at 19-21. But Issak (at 31-35) says the Court cannot yet resolve this immunity. Issak exaggerates the Sixth Circuit's "'general preference' for deciding qualified immunity at . . . summary[ ]judgment," when it has also held that district courts "must adjudicate a motion to dismiss on [these] grounds." *Sterling Hotels, LLC v. McKay*, 71 F.4th 463, 466-67 (6th Cir. 2023) (citations omitted)). Indeed, this defense calls for early resolution to protect officials from discovery. *Pearson v. Callahan*, 555 U.S. 223, 231-32 (2009).

Qualified immunity applies because IRB review does not violate a clearly established right. Dkt. 41 at 20. In claiming it does, Issak (at 32) cites broad legal principles and insists "near-identical facts" are not required. But, Issak must identify "a case with a fact pattern similar enough" to warn state officials "about what the law requires," a case that "places the constitutional question beyond debate." *Guertin v. State*, 912 F.3d 907, 932 (6th Cir. 2019) (citation omitted). She cites no such case.

Constitutional Claims. Issak does not dispute that any facial challenge must fail. Dkt. 41 at 21. But her as-applied arguments also fail because IRB review (1) targets conduct and, thus, does not warrant strict scrutiny; (2) does not target content, speaker, or viewpoint and passes intermediate scrutiny; and (3) is not an unconstitutional prior restraint or (4) an unconstitutional condition.

1. IRB review regulates conduct, not speech, so it receives and survives rational-basis review. Dkt. 41 at 22-25. Issak says (at 14-16) that IRB review demands heightened scrutiny because it is triggered by her dissertation, which will contribute to generalizable knowledge. Not so. IRB review is triggered because Issak will *conduct research* in the form of a "systematic investigation . . . designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(l). If the research was already gathered and deidentified, then Issak could write a dissertation contributing to generalizable knowledge without IRB review. 45 C.F.R. §§ 46.101(a), 46.102(e)(1)(ii); Dkt. 41-3 at 9. Or, as another example, if she conducted a systematic investigation to contribute to generalizable knowledge but

ultimately wrote a dissertation "focus[ed] directly on . . . specific individuals," IRB review would still have been needed. 45 C.F.R. § 46.102(l)(1). In sum, the trigger for IRB review is not the resulting dissertation—it is the scope and purpose of the contemplated research.

Issak also suggests (at 15) that IRB review regulates speech because, if she were not contributing to generalizable knowledge, she could gather "the same information" without IRB review. She oversimplifies the results from two different forms of information gathering. It is true that during systematic investigations and individual-focused scholarly activities the information gatherer might ask the same questions to the same individuals, resulting in an *overlap* of information for both approaches. 45 C.F.R. § 46.102(l)(1); Dkt. 41 at 29. But the information-gathering process for the scholarly activities "can be designed to . . . deliberately expose the individuals to public scrutiny or even possible harm," while research requiring IRB review should *not* do this. *Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements*, HHS.gov (July 19, 2018), perma.cc/9GVQ-DCPR; 45 C.F.R. § 46.111(a)(1). Further, the purpose of the scholarly activities is to produce information focused on specific individuals, while the purpose of research is to produce information focused on the "community or group" to which the individuals belong. *Id.* The different risks and purposes in each approach result in different *bodies* of information. *Id.*; 82 Fed. Reg. 7149-01, at 7174-75 (Jan. 19, 2017). And it is these differences that trigger IRB review for human-subjects research—not Issak's plan to write a dissertation contributing to generalizable knowledge.

Next, Issak says (at 16-17, 20) her research is protected because it will be "communicative," taking the form of spoken words in interviews. But words alone do not make interviews protected speech. Dkt. 41 at 22-25. Indeed, her interviews do not even qualify as expressive conduct (which would only merit intermediate scrutiny). *Id.* at 28. To be expressive conduct, the interviews "must 'convey a particularized message' that someone viewing the [interview] would most likely understand." *Yoder v. Bowen*, 146 F.4th 516, 529 (6th Cir. 2025) (citation omitted); *Lichtenstein v. Hargett*, 83 F.4th 575,

594-96 (6th Cir. 2023). Issak does not claim this of her interviews.

Finally, deferential review is appropriate because UT must be able to supervise Issak's attempts to act in its name. Dkt. 41 at 25-27. Issak does not dispute that her research would be affiliated with UT. Still, she (at 22-23) calls for discovery, arguing IRB review does not serve a legitimate pedagogical purpose. She is twice mistaken. First, no discovery is needed. Whether IRB review is reasonably related to legitimate pedagogical concerns "is a question of law," *Poling v. Murphy*, 872 F.2d 757, 762 (6th Cir. 1989), which the Court can resolve with no "evidentiary showing" from Defendants, *Lichtenstein*, 83 F.4th at 596-601 (citation omitted). Second, teaching respect for others is a legitimate pedagogical concern. *Poling*, 872 F.2dat 762. And this lesson is *tied* to Issak's dissertation. She cannot apply to the IRB without the approval of her dissertation advisor, who is the principal investigator for her research. Dkt. 34 ¶ 101-18; Dkt. 41-4 at 378, 470; *see* Dkt. 41-3 at 23. Further, while the IRB's academic expertise may differ from her dissertation committee's, the IRB can obtain an anthropology consultant to aid its review. Dkt. 41-3 at 53-54. Thus, UT's interests are legitimate and protected by deferential scrutiny.

2. Even under heightened scrutiny, IRB review would pass muster. Dkt. 41 at 27-32. Issak disagrees (at 16-22), arguing that IRB review is content, speaker, and viewpoint based. All three claims rely primarily on her mistaken understanding of what triggers IRB review. *Supra* at 4-5. She also (at 18-20) disputes that IRB review depends on the purpose of the research by quoting a comment about function and purpose in *Reed v. Town of Gilbert*, 576 U.S. 155 (2015), that, when "[c]onsidered in context . . . has little bearing on our case," *Mar. v. Mills*, 867 F.3d 46, 58 (1st Cir. 2017). The challenged ordinance in *Reed* depended on a sign's "communicative content"; IRB review depends on the risks and purposes of contemplated research and does not restrict based on a message. *Id.*; *see Siders v. City of Brandon*, 123 F.4th 293, 304-05 (5th Cir. 2024); 82 Fed. Reg. at 7174-75.

Next, Issak claims (at 23-24) that the Court cannot yet decide whether IRB review satisfies any level of scrutiny. But the Sixth Circuit disagrees, having recently resolved a First Amendment

question under intermediate scrutiny on an appeal from a dismissal. *Lichtenstein*, 83 F.4th at 582, 596-601. Despite calling for discovery, Issak goes on (at 25-28) to argue that the IRB review requirement inadequately furthers Defendants' interests. But UT's SOPs and federal regulations "alone" demonstrate both the legitimacy of Defendants' interests and how IRB review is sufficiently tailored to further those interests. *Lichtenstein*, 83 F.4th at 596-601; Dkt. 41 at 30-32.

Documents central to the Complaint also show the interest in protecting Issak's research subjects carries special weight. Issak acknowledges that her research subjects are governed by UAE's Kafala system. Dkt. 41-4 at 389-90. Under this system, immigrants depend entirely on their employers to enter and remain in the UAE, and they have few rights.[2] Yet, Issak plans to observe and analyze her subjects' acts of resistance against their employers, which could place these women at great risk. Dkt. 41-4 at 380-81; Dkt. 41-6 at 1. While Issak (at 26) quotes an excerpt from the Federal Register to claim that these women are adequately protected by their ability to consent and would understand the risk of their participation—the quoted material was discussing an *exemption* from the application of federal regulations for *non-invasive, low-risk* research. 80 Fed. Reg. 53,933-01, at 53,951-52 (Sept. 8, 2015) (describing what would become 45 C.F.R. § 46.104(d)(2)). Issak's research is neither.

Finally, Issak questions whether IRB review effectively protects human subjects. She points (at 25) to the challenges in measuring its benefits. But the Supreme Court has "never required" governments to prove the efficacy of every action "with empirical data." *Los Angeles v. Alameda Books, Inc.*, 535 U.S. 425, 439 (2002). Governments generally need only show their actions "advance[]" important interests, *Free Speech Coal., Inc. v. Paxton*, 606 U.S. 461, 495 (2025), which they can do "by reference to studies and anecdotes pertaining to different locales . . . and history, consensus, and simple common sense," *Missouri ex rel. Nixon v. Am. Blast Fax, Inc.*, 323 F.3d 649, 656 (8th Cir. 2003) (cleaned

[2] Josh Cohen, *Screen Door, Side Door, Closed Door: How Immigration Policies for Three Homogenous States Are Decidedly Not 'Open'*, 34 Geo. Immigr. L.J. 663, 676-77 (2020).

up, citation omitted). The history of the IRB and its adoption by 17 federal agencies show consensus that this process furthers its purpose. Dkt. 41 at 1-6. Issak also questions (at 27-28) if IRB review can be effective since it is not required for individual-focused scholarly activities. But IRB review is designed for the unique harms arising from systematic investigations with a generalizable scope. *See Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1066-67 (Ariz. Ct. App. 2008); Lainie Ross, *Human Subjects Protections in Community-Engaged Research*, J. Empir. Res. Hum. Res. Ethics (Sept. 27, 2010), perma.cc/Z5MA-J3CX. Separate tools protect subjects of individual-focused scholarly activities.[3]

3. IRB review is not an unconstitutional prior restraint. Dkt. 41 at 32-34. In asserting that it is, Issak (at 28-29) ignores Defendants' many examples of the limits on IRB's discretion and cherry picks phrases from UT's SOPs—phrases clearly limiting discretion—to assert that the IRB's assessments are impermissibly subjective. This erroneously conflates "sufficient discretion" with "unbridled discretion." *See G.K. Ltd. Travel c. City of Lake Oswego,* 436 F.3d 1064, 1082-84 (9th Cir. 2006).

4. IRB review imposes no unconstitutional condition on Issak's Ph.D. Dkt. 41 at 34. Issak (at 29-31) again fails to recognize that review turns on the risks and purposes of her research, not any message, so it is a *constitutional* requirement. *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 913 (6th Cir. 2019). And, to impose an unconstitutional condition, a government must require the *surrender* of a constitutional right in exchange for a benefit. *Id.* at 912-13. Issak tries to avoid that principle by pointing out (at 30) that Defendnats' cases are about "government funding programs." The cited cases do not say they are so limited. They say unequivocally a government cannot condition a "benefit" on someone "giving . . . up" a right. *Planned Parenthood*, 917 F.3d at 912 (citation omitted). Here the "benefit" is Issak's Ph.D., and UT has not conditioned this benefit on her *surrendering* her ability to research human subjects. Thus, Defendants' motion to dismiss should be granted.

[3] *See, e.g.*, *Ethical Journalism*, NY Times (Mar. 26, 2025), perma.cc/JR2L-TKF6; *Oral History Association Statement of Ethics*, Oral History (2025), perma.cc/L9ZP-T4XM.

Respectfully submitted,

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