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

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

PLAINTIFF'S OPPOSITION TO MOTION TO DISMISS

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INTRODUCTION

The government Defendants' demand for prior review of Plaintiff Idil Issak's communicative research prevents her from beginning the interviews necessary to complete her PhD in anthropology and from publishing her findings—even though her Doctoral Committee already approved her proposed academic research. The IRB Mandate constitutes a content, speaker, and viewpoint-based restriction on Ms. Issak's speech and an unconstitutional condition on her obtaining a PhD. But for Defendants' prior restraint, Ms. Issak could begin surveying domestic workers in the United Arab Emirates and complete her PhD dissertation. As such, the IRB Mandate represents an unconstitutional abridgement of Ms. Issak's First Amendment right to freedom of speech.

Ms. Issak's Amended Complaint timely and plausibly alleges multiple ongoing violations of her First Amendment rights caused by the IRB Mandate. Defendants are not immune to liability for the harms they have caused and could bring to an end, the IRB Mandate is not justified by or tailored to the interests the Defendants advance, and their offer of some 700 pages of exhibits to justify dismissal at the Motion to Dismiss stage is inappropriate. Defendants' motion should be denied.

BACKGROUND

As set forth in the Amended Complaint, spurred by her personal observation of exploited female foreign servants in the UAE, Ms. Issak seeks a PhD to expose and redress the suffering of these women. ECF34 ¶¶31–36. Ms. Issak's research is not federally funded and contrary to Defendants' suggestion that federal regulations force them to subject Ms. Issak to the IRB Mandate, ECF41 at 11, federal regulations only require IRB approval for research funded by a federal department or agency. *See* 45 C.F.R. § 46.101(a).[1] Further, the regulations do <u>not</u> require Defendants to incorporate the federal IRB standards into their "federal-wide assurance" or FWA Application:

[1] That is not to say that the federal regulations are constitutional, but this case does not challenge those regulations. *See* ECF34 at 4 n.2.

Rather, federal regulations merely require Defendants to provide "an appropriate existing code, declaration … or statement of ethical principles, … or [] a statement formulated by the *institution* itself."[2] In short, Defendants voluntarily opted to require Ms. Issak and other researchers who are not funded by the federal government to comply with the IRB Mandate.

Defendants' Background section provides an abbreviated discussion of the development of the IRBs, framing the University's decision to force Ms. Issak to comply with the IRB Mandate as necessary given the horrors of Nazi war criminals' experimentation on prisoners and the "infamous syphilis study in Tuskegee." ECF41 at 2, 1. But discussing the atrocities of the Nazi regime and the U.S. Public Health Service's[3] inhumane treatment of African-American men—both of which involved dangerous government conduct in research, not just private speech—is a rhetorical tactic that has nothing to do with Plaintiff's as-applied challenge to the University of Tennessee applying its IRB Mandate to the social science research in this case. Plaintiff therefore will not waste judicial resources responding here. More importantly, as discussed below, such generalized alleged government interests warrant discovery but do not satisfy constitutional scrutiny. In any event, Ms. Issak's communicative research entails pure speech, which does not raise the unique safety issues that may arise in the context of medical or other physical research.

ARGUMENT

I. THIS COURT HAS SUBJECT MATTER JURISDICTION

Defendants' ongoing control over Ms. Issak's speech, including by exercising the power to determine whether her research is culturally appropriate, provides Ms. Issak standing. Additionally, the IRB is not an arm of the state and thus not entitled to sovereign immunity, or alternatively,

[2] *Federalwide Assurance (FWA) for the Protection of Human Subjects*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html (last visited Sept. 29, 2025) (emphasis added).

[3] *The U.S. Public Health Service Untreated Syphilis Study at Tuskegee*, CDC (Sept. 4, 2024), https://www.cdc.gov/tuskegee/about/index.html.

jurisdictional discovery is necessary to determine whether the IRB is an arm of the state. Accordingly, Defendants' Motion to Dismiss under Rule 12(b)(1) should be denied.

A. Ms. Issak Has Standing to Challenge the IRB Mandate's "Culturally Appropriate" Standard

The full IRB has yet to consider Ms. Issak's IRB Application, and thus the full IRB has yet to assess whether her research is "culturally appropriate," ECF34 ¶¶5, 78, 93–94, 202–04, which constitutes a viewpoint-based determination. Ms. Issak therefore remains subject to this element of the IRB Mandate and has standing to pursue that theory against the IRB and Official-Capacity Defendants—the Defendants against whom Ms. Issak seeks prospective relief.

Defendants' argument to the contrary relies on exhibits indicating Defendant Beebe stopped seeking information from Ms. Issak concerning whether her research is culturally appropriate. ECF41 at 18. That fact, however, is irrelevant because, as Defendants stressed in their opening brief, the entire IRB has yet to consider Ms. Issak's IRB Application. All that has been decided so far is that Ms. Issak provided the required letter of cultural appropriateness: The IRB as a body has yet to decide whether Ms. Issak's proposed research is culturally appropriate. *See* ECF41 at 11 ("first, IRB staff conduct a preliminary review to ensure that the research proposal is complete and ready for review by the full IRB; second, the full IRB committee will review and vote on whether to approve, modify, or reject the proposal"); *id.* (Ms. Issak "never made it past step one of IRB review"). Further, because the IRB is charged with conducting an "*ongoing review* of international research," Ms. Issak remains subject to the cultural-appropriateness requirement that the IRB has adopted in implementing the SOPs. *See* ECF34 ¶93 (IRB requires "Memo of Cultural Appropriateness" signed by individual with "cultural and regulatory knowledge"); *SOP*s[4] at 236–37 (discussing IRB responsibilities for transnational research as making sure "the investigator has obtained the appropriate host country approvals and

[4] *SOP*s, Research Integrity & Assurance, UNIV. OF TENN. (Feb. 1, 2025), https://research.utk.edu/research-integrity/human-research-protection-program/for-researchers/.

permissions to conduct the proposed research"); *id.* at 238 ("The IRB is responsible for the *ongoing review* of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations… .") (emphasis added). Accordingly, Ms. Issak has standing to challenge the viewpoint-based "culturally appropriate" standard the IRB adopted.

Ms. Issak also has standing to obtain the nominal damages she seeks from the Individual-Capacity Defendants for their imposition of a viewpoint-based abridgement of her speech. *See Reform Am. v. City of Detroit, Mich.*, 37 F.4th 1138, 1148 (6th Cir. 2022) (the party "must show standing to seek each … remed[y]" and the party "no doubt may seek nominal damages to redress the asserted past violations of constitutional rights"). Here, it is noteworthy that the Individual-Capacity Defendants did not seek dismissal of Ms. Issak's First Amendment claim based on a lack of standing.

B. The IRB Mandate's Prior Restraint Chills Ms. Issak's Speech, Providing Standing

Ms. Issak has standing to challenge the prior restraint scheme Defendants impose through the IRB Mandate because the Amended Complaint plausibly alleges the IRB Mandate chills her speech. ECF34 ¶¶5–8, 135–49. Defendants' argument that they did not "even imply she should narrow the scope of her research," ECF41 at 26, is irrelevant because the government need not suggest a speaker self-censor to abridge the First Amendment.

Defendants argue that they did not cause any injury to Ms. Issak because her self-censorship "was self-inflicted." ECF41 at 25. That, however, is not the test. Rather, the very concept of an unconstitutional "chilling of speech" rests on the risk of self-censorship. Case law holds that a "subjective chill" is actionable if the plaintiff alleges "a concrete harm—i.e., enforcement of a challenged statute—occurred or is imminent." *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 764 (6th Cir. 2019) (cleaned up). Ms. Issak did not merely allege a "subjective" chilling of her speech: She also alleged Defendants enforced the IRB Mandate on her communicative research by directing her on multiple occasions to revise her IRB application. Additionally, the University Official-Capacity Defendants implemented a new IRB process for Ms. Issak and other PhD candidates being advised by Dr. Swamy—students are "not allowed to directly contact the IRB and [] instead they must submit their IRB applications to Dr. Swamy, and from there, the application would be routed to the Department Head (Heath), the Arts and Science Divisional Dean (Grzanka), and Associate Research Dean (Blum), and then to Withrow, and finally the IRB committee." ECF34 ¶103. Instituting this multi-step process increases the risk of a rejection by any one of the individual reviewers which further chills Ms. Issak's speech and delays her research. Thus, Ms. Issak's Amended Complaint properly pleaded both that her speech was chilled, as her "most recent application to the IRB contains only 25% of the content she originally intended to research[,]" ECF34 ¶148, and that Defendants enforced the IRB Mandate against her. Further, even if the IRB eventually approves Ms. Issak's application, should she engage in any speech beyond that approved she would be subject to disciplinary action. ECF34 ¶136. That threat of punishment further chills Ms. Issak's speech.

Finally, Defendants' reliance on *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013), is misplaced. In *Clapper*, the "self-inflicted injury" was the plaintiffs' expenditure of funds to protect the privacy of their communications that the government may—or may not—later intercept. *Id.* at 402. The plaintiffs in *Clapper* did "not face a threat of certainly impending interception under [the challenged statute]." *Id.* at 417. Because the plaintiffs lacked the threat of the government intercepting their communications under the statute, the Supreme Court held the only claimed injury, i.e., the cost of avoiding surveillance, was a self-inflicted harm insufficient to establish standing. *Id.* at 418.

Laird v. Tatum, 408 U.S. 1 (1972), on which *Clapper* relied, similarly stressed that a party "must show that *he has sustained, or is immediately in danger of* sustaining, a direct injury as the result of" defendants' action. *Laird*, 408 U.S. at 13 (cleaned up) (emphasis added). Unlike *Clapper* and *Laird*, where the plaintiffs failed to show a likelihood that their speech would be targeted, Ms. Issak's injury is not hypothetical: Defendants made clear she *cannot* conduct her research until the IRB approves her application or she will put her PhD at risk.[5] ECF34 ¶136. In short, *Clapper* and *Laird* are inapplicable. Ms. Issak is and will continue to be harmed so long as the IRB Mandate applies and she therefore has standing.

C. The IRB Is Not an Arm of the State and Is Not Entitled to Sovereign Immunity

Defendants argue that this Court lacks jurisdiction over the IRB based on Eleventh Amendment sovereign immunity.[6] ECF41 at 22–24. But that immunity is limited to states or "arm[s] of the state." *See Laborers' Int'l Union of N. Am., Local 860 v. Neff*, 29 F.4th 325, 330 (6th Cir. 2022). And while case law holds that a state-established university in Tennessee qualifies as an "arm of the state," whether an at least quasi-independent IRB is also an arm of the state is an issue of first impression, controlled by federal law. *See Regents of the Univ. of Calif. v. Doe*, 519 U.S. 425, 432 n.5 (1997) (explaining the arm of the state analysis is a "question of federal law" based on how state law "define[s] the agency's character"). To answer that question, courts consider four factors:

> (1) the State's potential liability for a judgment against the entity, … ; (2) the language by which state statutes, … and state courts, … refer to the entity and the degree of state control and veto power over the entity's actions, … ; (3) whether state or local officials appoint the board members of the entity, … ; and (4) whether the entity's functions fall within the traditional purview of state or local government[.]

Ernst v. Rising, 427 F.3d 351, 359 (6th Cir. 2005).

To the extent there is public evidence, as cited in the Amended Complaint, ECF34 ¶¶59–67, or Defendant-supplied evidence concerning the IRB's character, the four factors courts consider in

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[5] *Human Research Protection Program FAQs*, UNIV. OF TENN., https://research.utk.edu/research-integrity/human-research-protection-program/human-research-protection-program-faqs/ ("If you have conducted or are conducting human subjects research without IRB approval, you are ... subject to non-compliance and research misconduct reporting to university officials.") (last visited Sept. 29, 2025).

[6] The Official-Capacity Defendants appropriately do not argue they are entitled to sovereign immunity. Accordingly, even if this Court finds dismissal of the IRB appropriate, the claims against the Official-Capacity Defendants remain.

determining whether an entity is an "arm of the state" are split. Defendants maintain the first factor, weighs toward the IRB being considered an "arm of the state" because the "IRB is a state-funded subsidiary of UT and, thus, a judgment against it would be paid by Tennessee." ECF41 at 21–22. Without discovery, Plaintiff lacks the ability to probe this assertion and understand what it means to say the IRB is "state-funded" and a "subsidiary." To this point, the University submits a declaration attesting that "UTK uses its own funds, obtained through the State and sponsored projects, to pay compensation and salaries to IRB staff and to pay all other expenses necessary to operate the IRB," but that statement leaves much unknown. ECF41-7 at 2. What are "sponsored projects?" Are they "federal projects?" Are they projects funded by foreign governments? And if either, how much relative funding comes from foreign or federal grants? Discovery would also reveal whether Tennessee has ever paid out a judgment on behalf of the IRB or instead, denied fiscal responsibility. Likewise, discovery is needed to understand what Defendants mean by saying the IRB is a "subsidiary" of the University and what, if any, entity was formed and under what terms. Deciding this factor would be premature without discovery.

Conversely, the second factor,[7] namely "the language by which state statutes and state courts refer to the entity and the degree of state control and veto power over the entity's actions," indicates the IRB is not an "arm of the state." *Kreipke v. Wayne State Univ.*, 807 F.3d 768, 775 (6th Cir. 2015). First, unlike Tennessee's creation of a university system which is established by statute, TENN. CODE ANN. § 49-9-101 *et seq.* (2023), there does not appear to be any state statute creating the IRB, only references to federal regulations regarding human subjects. *See* TENN. CODE ANN. §§ 47-18-3311(a)(10)(A) (2025) ("in accordance with the federal policy for the protection of human subjects

[7] Defendants mischaracterize the second factor as "*UT*'s *characterization* of and control over the IRB[,]" ECF41 at 22 (emphasis added); however it is how the "the language by which state statutes, … and state courts, … refer to the entity[,]" *Ernst v. Rising*, 427 F.3d 351, 359 (6th Cir. 2005), that matters.

under 45 CFR Part 46" and "under 21 CFR Parts 6, 50, and 56"); 47-18-4902 (2023) (citing federal statutes); 47-18-4903 (2023) (same); 47-18-4904 (2023) (same); 63-6-1302 (same). Tennessee state court decisions also lack an analysis of the structure of IRBs.

The pre-discovery evidence also indicates Tennessee does not control the IRB; the SOPs are littered with statements distancing the University from the IRB and stressing IRB's independence and final authority over research. *See* ECF34 ¶¶62–64; *SOP*s, *supra* note 4, at 20 (describing the Institutional Official's ("IO") job as "[e]nsuring that the IRB functions *independently*") (emphasis added); *id.* at 22 ("The IRB functions independently ... [and] makes independent determinations whether to approve, require modification in, or disapprove research, ..."); *id.* at 49 ("The IRB functions independently."). Similarly, Defendant Wyatt, the IRB's Interim IO, spoke of the IRB as "an independent entity separate from the [Human Research Protection Program] of the University." ECF34 ¶62.

Finally, the University lacks veto power over the IRB. While Defendants seem to suggest otherwise by noting "UT has the authority to 'disapprove' research that has been approved by the IRB," ECF41 at 23 (citing *SOP*s, *supra* note 4, at 8–9, 21, 49), Defendants ignore the fact that "no one at The University of Tennessee Knoxville shall approve the implementation of human subject research that has not been approved by the IRB *nor may anyone override a decision of the IRB*." *SOP*s, *supra* note 4 at 8–9 (emphasis added). In short, Tennessee does not control the IRB. The second factor therefore weighs in favor of finding the IRB is not an arm of the state. Alternatively, to the extent there is any question about Tennessee's control over the IRB, discovery would be needed, making dismissal of the IRB improper at this juncture.

On the third factor, Ms. Issak acknowledges the University appoints individuals to serve on the IRB. But the University's authority over the IRB ends there. *See supra* at 8. Further, no one factor is dispositive. *See Kreipke*, 807 F.3d at 777–78 (explaining that "caselaw analyzing Eleventh Amendment immunity" weighs and balances the arm of the state factors "against each other based on the unique circumstances of the case"). Accordingly, the University's appointment of IRB members does not compel the conclusion that the IRB is an arm of the state.

The fourth factor, which considers "whether the entity's functions fall within the traditional purview of state or local government," *Ernst*, 427 F.3d at 359, supports the conclusion that the IRB is not an arm of the state. To start, establishing a prior restraint on speech in violation of the First Amendment cannot be said to be a "traditional" state function. *See Staub v. City of Baxley*, 355 U.S. 313, 322 (1958) (a restriction that "makes the peaceful enjoyment of freedoms which the Constitution guarantees contingent upon the uncontrolled will of an official—as by requiring a permit or license which may be granted or withheld in the discretion of such official—is an unconstitutional censorship or prior restraint upon the enjoyment of those freedoms"). Additionally, Defendants assert the IRB's function is to comply with controlling federal regulations, "much in the nature of contract: in return for federal funds, the States agree to comply with the federally imposed conditions." ECF41 at 24 (citation omitted). Satisfying federal conditions, however, is a proprietary function, not limited to government entities but within the "traditional purview" of any federal grantee, including private entities. *See C.K. v. Bell Cnty.*, 839 F. Supp. 2d 881, 885 (E.D. Ky. 2012) ("Governments perform proprietary functions when they engage in a business of a sort … engaged in by private persons or corporations for profit.") (cleaned up). *Cf. Ciraci v. J.M. Smucker Co.*, 62 F.4th 278, 283 (6th Cir. 2023) (discussing whether an entity was a private or public actor, stating "[b]ut federal contracts by themselves do not create the requisite entwinement" to become a public actor) (quoting *Rendell-Baker v. Kohn*, 457 U.S. 830, 841 (1982)). As such the IRB's function of ensuring contractual compliance falls outside "the traditional purview of state governments."[8] ECF41 at 23. This factor thus also weighs in favor of a finding that the IRB is not an "arm of the state."

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[8] Defendants assume the IRB serves a pedagogical function—something yet to be established—when asserting that furthering higher education is a traditional state function. ECF41 at 23.

Taken together, the balance of these factors supports the conclusion that the IRB is not an arm of the state.[9] Alternatively, this Court should withhold a decision concerning whether the IRB is an "arm of the state" pending the completion of jurisdictional discovery. *See Rogers v. Stratton Indust., Inc.*, 798 F.2d 913, 918 (6th Cir. 1986) (explaining that when defendants seek 12(b)(1) dismissal, the nonmoving party must "be afforded an ample opportunity to secure and present evidence relevant to the existence of jurisdiction"); *see also Missouri v. Biden*, No. 22-cv-01213, 2024 WL 5316601, at *2 (W.D. La. Nov. 8, 2024) (granting plaintiffs jurisdictional discovery on remand from Supreme Court).

II. Rule 12(b)(6) Dismissal Is Inappropriate Because Ms. Issak Has Stated Plausible First Amendment Claims

Ms. Issak has plausibly alleged First Amendment claims under multiple theories making dismissal of the complaint inappropriate under Rule 12(b)(6). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. … A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.") (quotations and citations omitted).

Initially, Defendants wrongly maintain that under Rule 12(b)(6), this Court can consider hundreds of pages of evidence they attached to their Motion to Dismiss, citing *Diei v. Boyd*, 116 F.4th 637, 644 (6th Cir. 2024)). ECF41 at 26. While *Diei* allows for consideration of exhibits "referred to in the Complaint [that] are central to the claims contained therein[,]" as well as "public record[] or [materials that] are otherwise appropriate for the taking of judicial notice[,]" *Diei* made clear that certain evidence was improper to consider. *Id.* at 643; *id.* at 644 (determining that introducing pledges plaintiff signed and screenshots of her social media posts was improper). Further and significantly, the court in *Diei* held the district court erred by considering that evidence and dismissing the complaint

[9] Because the IRB is not an arm of the state it is a person for purposes of § 1983. *See McKenna v. Bowling Green State Univ.*, 568 F. App'x 450, 456 (6th Cir. 2014).

without allowing the plaintiff to conduct discovery to "have an opportunity to counter those items with other evidence." *Id.* at 644. *See also ELG by Till v. King*, 784 F. Supp. 3d 983, 989 (E.D. Mich 2025) (citing *Diei* for the proposition that if "extra-complaint materials are to be considered, the Court must convert the motion to a motion for summary judgment under Rule 56 and allow all parties to present evidence, which usually means that an opportunity to conduct discovery should be given").

Under Sixth Circuit precedent, then, before relying on the hundreds of pages of material Defendants submit in support of their Motion to Dismiss, Ms. Issak is entitled to an opportunity to conduct discovery to counter Defendants' evidence. This Court should either disregard any evidence presented outside the Amended Complaint and consider solely the well-pleaded allegations or deny the motion without prejudice for Defendants to renew the motion as one for summary judgment following discovery. *See* FED. R. CIV. P. 12(d) ("If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion."). However, as shown below, even considering the additional evidence cited by Defendants, their Rule 12(b)(6) Motion to Dismiss should be denied.

A. Ms. Issak's Claims Are Not Barred by the Statute of Limitations

Defendants have not met their burden of proving Ms. Issak's claims are barred by the statute of limitations because the unconstitutional IRB Mandate applies and *will continue to control* Ms. Issak's research even after it is initially approved and thus Ms. Issak's injury is ongoing. *See Campbell v. Grand Trunk W.R.R. Co.*, 238 F.3d 772, 775 (6th Cir. 2001) (explaining defendants have the burden of proving plaintiff's claims are barred by the statute of limitations).

The Sixth Circuit has made clear that a § 1983 claim is not barred by the statute of limitations if the law or policy challenged continues to violate a plaintiff's rights. *See Kuhnle Bros., Inc. v. Cnty. of Geauga*, 103 F.3d 516 (6th Cir. 1997). While Defendants claim Ms. Issak's claims are barred by

Tennessee's one-year statute of limitations that governs § 1983 claims because she knew or should have known of the IRB Mandate years before she filed suit on June 2, 2025, ECF41 at 27, the fact remains that Ms. Issak is and will be subject to the unconstitutional IRB Mandate throughout her research. Under *Kuhnle*, then, Ms. Issak's claims are timely.

In *Kuhnle*, the plaintiff, a trucking company, brought multiple constitutional claims under § 1983, challenging a county resolution that prohibited the plaintiff from operating its vehicles on certain municipal roads. 103 F.3d at 518–19. The lower court found the claims were time-barred. *Id.* at 518. The Court of Appeals reversed in part. It held plaintiff's takings and substantive due process claims, premised on a deprivation of a property right, were barred by the statute of limitations because those injuries occurred at a specific point in time—when the resolution's enactment caused the alleged taking. *Id.* at 521. In contrast, the court held the plaintiff's substantive due process claim for interference with interstate travel was a continuing violation because the plaintiff "suffered a new deprivation of constitutional rights every day that [r]esolution [] remained in effect." *Id.* at 522–23. Accordingly, the Sixth Circuit held the plaintiff's interstate travel claim was not time barred, stressing the "continued enforcement of an unconstitutional statute cannot be insulated by the statute of limitations." *Id.*

Following its decision in *Kuhnle*, the Sixth Circuit has explained that a plaintiff's claim is not barred by the statute of limitations "when (1) the defendant[] engaged in continuing wrongful conduct; (2) the injury to the plaintiff[] accrue[d] continuously; and (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided." *Hensley v. City of Columbus*, 557 F.3d 693, 697 (6th Cir. 2009). Under this test and *Kuhnle*, Ms. Issak's First Amendment claims are timely.

First, Defendants have continually applied the IRB Mandate to social science communicative research, and specifically to Ms. Issak. Consequently, Ms. Issak's First Amendment injury—being subjected to the unconstitutional IRB Mandate—accrues continuously. Further, if Defendants cease subjecting Ms. Issak to the IRB Mandate, she could immediately begin her research and no longer suffer an injury to her First Amendment rights. In other words, like the plaintiff's right to interstate travel in *Kuhnle*, Ms. Issak's First Amendment injuries are continuing and ongoing every day the IRB Mandate remains in place. *See also Flynt v. Shimazu*, 940 F.3d 457, 462 (9th Cir. 2019) (rejecting statute of limitations defense and citing *Kuhnle* to hold California's continued enforcement of a statute that barred out-of-state investors in casinos inflicted a continuing harm).

While Defendants ignore *Kuhnle*, they cite the wholly inapposite case of *Eidson v. Tennessee Department of Children's Services*, 510 F.3d 631 (6th Cir. 2007), to argue Ms. Issak's First Amendment claims are time-barred. ECF41 at 27–29. *Eidson*, however, involved a due process challenge to a concrete and completed action, namely, the state's removal of a custodial father's children from his home. 510 F.3d at 632–33. By contrast, Ms. Issak's challenge is not to a concrete and completed action, but to Defendants' continuing requirement that she subject her speech to prior approval and then conduct her research consistent with the limitations the IRB establishes.[10]

Because Ms. Issak suffers a continuous infringement of her ongoing First Amendment right to freedom of speech, the statute of limitations poses no obstacle to her claims. *See N.Y. Times Co. v. United States*, 403 U.S. 713, 715 (1971) (Black, J., concurring) (stating an injunction preventing the publication of the Pentagon Papers would "amount[] to a flagrant, indefensible, and continuing violation of the First Amendment" and "make a shambles of the First Amendment"); *see also Doe v. Whitmer*, 751 F. Supp. 3d 761, 837 (E.D. Mich. 2024) (holding plaintiff's challenge to Michigan's sex-offender statute was not barred by the statute of limitations because "the Sixth Circuit views a

[10] For a detailed analysis of the Sixth Circuit's continuing violation precedent in the context of § 1983, *see Doe v. Haslam*, No. 3:16-cv-02862, 3:17-cv-00264, 2017 WL 5187117, at *11–13 (M.D. Tenn. Nov. 9, 2017).

constitutional challenge to a statute that is alleged to continue to violate a plaintiff's rights on an on-going basis as timely so long as the violation continues").

B. Strict Scrutiny Applies Because the IRB Mandate Is a Content-Based Regulation of Fully Protected Speech, Not Conduct

1. Under *Holder*, *Sorrell*, and *Ragland*, the IRB Mandate Regulates Speech, Not Conduct

The Supreme Court's decisions in *Holder v. Humanitarian Law Project*, 561 U.S. 1 (2010), *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), and *Arkansas Writers' Project, Inc. v. Ragland*, 481 U.S. 221 (1987), compel the conclusion that the IRB Mandate is a content-based regulation of speech—not conduct. In *Holder*, plaintiffs challenged a ban on providing "material support" to designated terrorist organizations, arguing, among other things, that the criminal statute at issue prohibited them from providing First Amendment-protected legal and political advocacy training to groups the United States had designated as terrorist organizations. 561 U.S. at 14. In that case, as here, the government contended "that the only thing actually at issue in th[e] litigation [was] conduct." *Id.* at 27. The Supreme Court expressly rejected this argument, declaring: "The Government is wrong[.]" *Id.* The *Holder* Court explained that while the criminal statute at issue "generally function[ed] as a regulation of conduct," the decisive inquiry was whether, "as applied to plaintiffs[,] the conduct triggering coverage under the statute consist[ed] of communicating a message." *Id.* at 27–28. The Supreme Court reasoned that because the statute barred "communicat[ing] advice derived from 'specialized knowledge'" to a designated terrorist organization, but not conveying information from "general" knowledge, "speech" "trigger[ed]" the statute. *Id.* The statute, as applied, constituted a restriction on speech and not conduct, and thus heightened scrutiny applied, the Supreme Court concluded. *Id.* at 28.[11]

[11] While *Holder* held the statute at issue regulated speech and not conduct, the Supreme Court nonetheless upheld the constitutionality of the law given "the Government's interest in combating terrorism is an urgent objective of the highest order." *Holder*, 561 U.S. at 28. As discussed below, *see infra* at 25–28, Defendants lack a similar compelling interest to justify the IRB Mandate, and therefore it cannot survive strict scrutiny.

Holder made clear that what "trigger[s] coverage" controls the determination of whether a provision governs "speech" or "conduct." If the so-called "conduct" that "trigger[s]" coverage "consists of communicating a message," the law regulates speech. *Id.* Under *Holder's* analysis, then, it is dispositive that the IRB Mandate is triggered by the content of Ms. Issak's speech, namely that she will communicate a message to "contribute to generalizable knowledge." ECF34 ¶¶2, 69–75, 127–34. The IRB Mandate therefore regulates speech, not conduct, and is subject to strict scrutiny. *Id.*

The Supreme Court decision in *Sorrell* likewise establishes that the IRB Mandate regulates speech and not conduct. In that case, "data miners" sought to purchase and analyze information from pharmacies to "produce reports on prescriber behavior," which they would then sell to pharmaceutical companies for use in marketing. *Id.* at 558. A Vermont state law barred the sale, use, or transfer of records for marketing purposes, while allowing the same records to be sold or used for educational and other purposes. *Id.* at 559–60. Vermont defended the law against a First Amendment challenge by arguing the restriction regulated "conduct" and not speech, because it merely restricted the "use" of the information to target doctors in marketing efforts. *Id.* at 570. The Supreme Court rejected Vermont's argument, holding the statute imposed content and speaker-based burdens on protected speech, subjecting the law to strict scrutiny. *Id.* at 571.

Sorrell is also closely analogous to the present case, for in *Sorrell*, the law allowed third parties to purchase the same subscriber information, with the law merely restricting how they would *use* the information: Vermont allowed the information to be used for educational purposes, but not for marketing purposes. *Id.* at 564. The Supreme Court held the statute, by treating educational uses different from marketing purposes, created a content-based distinction that rendered the law unconstitutional. *Id.* at 580. Similarly, in this case, the Defendants allow researchers to obtain the same information from third parties, with the IRB Mandate applying only to those who seek to use the information to contribute to generalizable knowledge. Under *Sorrell*, then, the IRB Mandate constitutes a content-based regulation of speech subject to strict scrutiny. *Id.* at 570.

Finally, *Ragland* confirms that the IRB Mandate constitutes a content-based regulation of speech subject to strict scrutiny. In *Ragland*, a state statute established differing taxes based on whether a publication was a "general interest" magazine or a religious, trade, professional, and sports one. 481 U.S. at 223. The Supreme Court held that law was a content-based regulation because "a magazine's tax status depend[ed] entirely on its *content*." *Id.* at 229. Like *Ragland*, the IRB Mandate distinguishes between "generalizable" and "non-generalizable" knowledge and thus represents a content-based restriction on speech that is subject to strict scrutiny.

2. Defendants' Argument that the IRB Mandate Regulates Conduct Relies on Inapplicable Precedent

Defendants seek to sidestep the speech at issue by focusing not on the IRB's detailed review of the speech in which Ms. Issak seeks to engage as part of her communicative research, but on some of the more tangential aspects of the IRB Mandate, such as the specific data-collection techniques the Defendants require. There are multiple problems with Defendants' argument. The first is that, because Ms. Issak seeks to conduct communicative research, review by the IRB necessarily focuses on her proposed speech—both in her interviews of the women and later in her dissertation. The second problem is that the IRB Mandate imposes both compelled conduct and compelled speech on Ms. Issak as a precondition for obtaining permission from the IRB to speak. The imposition of those preconditions for approval is *how* Defendants regulate her speech. Third, the IRB Mandate is facially a regulation of speech under *Holder* and *Sorrell*. Why? Because what "trigger[s] coverage" by the IRB Mandate is that Ms. Issak's "speech" will concern generalizable knowledge, *Holder*, 561 U.S. at 27, and by applying only to Ms. Issak's contribution of generalizable knowledge and not speech regarding non-generalizable knowledge, the IRB Mandate imposes content discrimination and is subject to strict scrutiny. *Sorrell*, 564 U.S. at 570.

Instead of grappling with *Holder*, *Sorrell*, and *Ragland*,[12] Defendants rely on *McLemore v. Gumucio*, 149 F.4th 859, 862–63 (6th Cir. 2025), ECF41 at 32–35, which involved a challenge to a state law requiring auctioneers to obtain a license. The Sixth Circuit found no violation of plaintiffs' First Amendment rights because, "[w]hile [p]laintiffs must speak to an audience or even craft narratives to sell products, their speech is incidental to the underlying sales transaction." *Id.* at 865 (cleaned up). By contrast, Ms. Issak's research consists entirely of speech: Her speech to third parties, their speech to her, and her speech advancing generalizable knowledge. *See Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (holding the creation and dissemination of information are speech within the meaning of the First Amendment); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (explaining a beer company engages in speech when it creates the "information on beer labels"); *Burson v. Freeman*, 504 U.S. 191, 207 (1992) (referring to "exit polling" as "other types of speech"); *Connick v. Myers*, 461 U.S. 138, 149–52 (1983) (characterizing a survey as "speech" and holding "[q]uestions, no less than forcefully stated opinions and facts, carry messages"); *see also ETW Corp. v. Jireh Publ'g, Inc.*, 332 F.3d 915, 924 (6th Cir. 2003) (explaining that "[t]he protection of the First Amendment is not limited to written or spoken words").

Defendants' reliance on *Lichtenstein v. Hargett*, 83 F.4th 575 (6th Cir. 2023), ECF41 at 37–38, is also misplaced. In *Lichtenstein*, plaintiffs challenged a Tennessee statute that "made it a crime for anyone other than election officials to distribute the state's official form for applying to vote absentee." 83 F.4th at 579. As the Sixth Circuit stressed, "Tennessee's ban prohibits an act: distributing a government form. This act qualifies as conduct, not speech." *Id.* The Court further held that "strict scrutiny does not apply to Tennessee's ban because it neutrally applies no matter the message that a

[12] Defendants fail to cite *Holder* and only cite *Sorrell* as supposed support for the proposition that strict scrutiny only applies if the speech is targeted because of its message. ECF41 at 32. However, as discussed below, a content-based law is subject to strict scrutiny regardless of whether the government targets the speech because of its content. *See infra* at 17–19.

person seeks to convey[.]" *Id.* Unlike *Lichtenstein*, the IRB Mandate does not apply "neutrally," but only applies if the "message that a person seeks to convey" concerns "generalizable knowledge." Under *Holder* and *Sorrell*, then, the IRB Mandate regulates speech and not conduct. Thus, the Defendants' motive is irrelevant and they are wrong that "prohibited targeting occurs only when expression has been 'target[ed] ... *because of* its message." ECF41 at 32 (quoting *Lichtenstein*, 83 F.4th at 592).[13]

The Supreme Court made that clear in *Reed v. Town of Gilbert*, 576 U.S. 155 (2015), explaining that because on its face, the government's ordinance regulating signs was "a content-based regulation of speech," the Court had "no need to consider the government's justifications or purposes for enacting the Code to determine whether it is subject to strict scrutiny." *Id.* at 164–65. In *Reed*, the Supreme Court distinguished between content-based regulations of speech which are subject to strict scrutiny regardless of the government's motive and "laws that, though facially content neutral," "were adopted by the government 'because of disagreement with the message [the speech] conveys.'" *Id.* at 164 (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)). Such facially-content neutral laws adopted because of the government's disagreement with the speech are also subject to strict scrutiny, the Court explained. *Id.* However, where, as here, *see supra* at 14–17, the IRB Mandate, on its face, is a content-based regulation of speech, the *Ward* standard does not apply and under *Reed*, Ms. Issak need not allege the Defendants targeted her speech because they disagreed with speech advancing generalizable knowledge. In short, *Lichtenstein* and the additional case law Defendants cite for the proposition that "prohibited targeting occurs only when expression has been 'target[ed] ... *because of* its messages'" is inapposite. ECF41 at 32 (quoting *Lichtenstein*, 83 F.4th at 592 (emphasis added by Defendants)).

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[13] *Ragland* confirms Ms. Issak need not establish the IRB Mandate is driven by an impermissible motive. In *Ragland*, where the Court applied strict scrutiny because of a speaker and content-based distinction, "there was no evidence that an illicit governmental motive was behind ... the tax[]." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 660 (1994) (discussing *Ragland*, 481 U.S. at 228–29).

Defendants do not address *Reed*, which makes clear that to be subject to strict scrutiny a content-based regulation need not target expression "'*because of* its messages." *Id.* Instead, Defendants quote out-of-context language from *City of Austin v. Regan National Advertising of Austin, LLC*, 596 U.S. 61, 74 (2022), that distinguished *Reed*. Defendants' reliance on *City of Austin*, however, is also misplaced.

In *City of Austin*, the plaintiffs challenged an ordinance that prohibited "off-premises billboards," i.e. billboards advertising something other than the goods or services offered at the location of the signage. *Id.* at 67. The plaintiffs in that case argued Austin's ordinance violated the First Amendment based on the Supreme Court's statement in *Reed* that "'[s]ome facial distinctions based on a message are obvious, defining regulated speech by particular subject matter, and others are more subtle, defining regulated speech by its function or purpose.'" *Id.* at 74 (quoting *Reed*, 576 U.S. at 163). Based on the "function or purpose" language from *Reed*, the plaintiffs in *City of Austin* argued that since the "purpose" of the ordinance was to prohibit off-site advertising, it constituted an impermissible content-based regulation on speech. *Id.*

The Supreme Court rejected that argument, noting that the plaintiffs stretched *Reed's* "'function or purpose' language too far." *Id.* "The principle the *Reed* Court articulated is more straightforward," the Supreme Court explained: "While overt subject-matter discrimination is facially content based (for example, 'Ideological Sign[s],' defined as those 'communicating a message or ideas for noncommercial purposes'), so, too, are subtler forms of discrimination that achieve identical results based on function or purpose (for example, 'Political Sign[s],' defined as those 'designed to influence the outcome of an election')." *Id.* (quoting *Reed* 576 U.S. at 159–60, 163–64). The Court in *City of Austin* summarized the principles as follows: "In other words, a regulation of speech cannot escape classification as facially content based simply by swapping an obvious subject-matter distinction for a 'function or purpose' proxy that achieves the same result. That does not mean that any classification that considers function or purpose is *always* content based." *Id.*

But contrary to Defendants' suggestion, that also does not mean that any classification that considers function or purpose is *never* content based. *City of Austin* held no such thing and Defendants' suggestion to the contrary comes from their grievous misread of *City of Austin*. In short, *City of Austin* does not stand for the proposition that a classification that considers the "function or purpose" of speech is content-neutral. Rather, the regulation of a "function or purpose" often equates to a regulation of content. *See Int'l Outdoor, Inc. v. City of Troy*, 974 F.3d 690, 703 (6th Cir. 2020) ("Regulation of speech is content-based and therefore subject to strict scrutiny 'if a law applies to particular speech because of the topic discussed or the *idea or message expressed*'; some obvious facial distinctions based on a message include 'defining regulated speech by particular subject matter' or 'by its function or *purpose*.'") (emphases added). *City of Austin*, however, was an outlier, where the ordinance considered the purpose of the sign merely to assess whether it was located on- or off-premises; the ordinance did not seek to regulate the content of the speech. *See* 596 U.S. at 71 (stressing the "sign's substantive message itself is irrelevant to the application of the provisions").

To the extent the IRB Mandate can be viewed as creating a "purpose-based" distinction—based on whether Ms. Issak's purpose is to convey a message of generalizable or non-generalizable knowledge—the IRB Mandate regulates the substance or content of speech, for the only way that a person can contribute to generalizable knowledge is to communicate somehow. It is not some unsaid purpose percolating in Ms. Issak's head that contributes to "generalizable knowledge," but the very words she uses in summarizing, analyzing, assessing, and expressing the information she gleans from the women she interviews. In other words, what differs between Ms. Issak's dissertation advancing "generalizable knowledge," and an oral historian's dissertation that does not advance "generalizable knowledge," is the *content* of speech written in the respective dissertations. And as the Supreme Court has stated, "if the act[] of ... 'publishing' information do[es] not constitute speech, it is hard to imagine what does fall within that category." *Bartnicki*, 532 U.S. at 527.

C. Strict Scrutiny Also Applies Because the IRB Mandate Imposes Speaker and Viewpoint-Based Restrictions

The IRB Mandate constitutes a speaker and viewpoint-based regulation of speech that requires strict scrutiny because it treats journalists and oral historians differently than anthropologists, and because determining the cultural appropriateness of the research is viewpoint specific. *See Bible Believers v. Wayne Cnty.*, 805 F.3d 228, 248 (6th Cir. 2015) (viewpoint-based regulation subject to strict scrutiny); *Sorrell*, 564 U.S. at 564 (speaker-based regulation subject to strict scrutiny). If Ms. Issak were a different type of speaker—one not seeking to contribute to generalizable knowledge—she would not need IRB approval. Additionally, requiring her research to be "culturally appropriate" subjects her speech to a viewpoint-based veto. *See Snyder v. Phelps*, 562 U.S. 443, 458 (2011) ("If there is a bedrock principle underlying the First Amendment, it is that the government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable.") (citation and quotation omitted).

As to the speaker-based discrimination claims, Defendants merely repeat their flawed argument based on their misreading of *City of Austin*, incorrectly positing that the IRB Mandate does not constitute a speaker-based restriction because it is the *speaker's purpose* of contributing to generalizable knowledge that triggers the IRB Mandate. ECF41 at 39. This argument fails because speakers only achieve their "research goal" by their choice of words, i.e. their speech. *See Sorrell*, 564 U.S. at 564 (holding that a prohibition on disseminating prescriber-identifying information, only if it would be used for marketing, was speaker-based because it targeted pharmaceutical manufacturers).

As to the viewpoint-based discrimination claims, Defendants argue Ms. Issak cannot state a claim of viewpoint discrimination because she cannot point to any more favored viewpoint, citing *Hartman v. Thompson*, 931 F.3d 471 (6th Cir. 2019) and *Viewpoint Neutrality Now! v. Regents of University* *of Minnesota*, 516 F. Supp. 3d 904 (D. Minn. 2021). ECF41 at 40. However, both cases are inapposite because they involved limited-public forums which were viewpoint-neutral. *Hartman*, 931 F.3d at 479–80 (fairgrounds with a designated protest zone was viewpoint-neutral); *Viewpoint Neutrality Now!*, 516 F. Supp. 39 at 922 (student service fees and campus limited public forum were viewpoint-neutral). By contrast, the IRB Mandate prohibits speech that fails to satisfy the cultural sensitivity of third parties. Allowing residents in other countries to prevent communicative research on the grounds that it is not culturally sensitive constitutes a viewpoint-based regulation.

Defendants' argument that the IRB Mandate's cultural-appropriateness requirement seeks not to regulate viewpoint, but to protect participants, fares no better. ECF41 at 40. This argument confuses the question of whether a statute is viewpoint-neutral with the question of whether the viewpoint-focus of the IRB Mandate is constitutionally justified.

Finally, Defendants attempt to avoid strict scrutiny by focusing on the university context in which Ms. Issak's constitutional challenge arises. Defendants argue that strict scrutiny does not apply because universities may "limit 'student speech in school-sponsored expressive activities so long as their actions are reasonably related to legitimate pedagogical concerns.'" ECF41 at 35 (quoting *Ward*, 667 F.3d at 742). Defendants add that schools have "special leeway" to regulate student speech that "others may reasonably perceive as 'bear[ing] the imprimatur of the school[.]" ECF41 at 35 (quoting *Mahanoy Area Sch. Dist. v. B.L. by & through Levy*, 594 U.S. 180, 187–88 (2021)).

These arguments fail because Ms. Issak's Amended Complaint alleges multiple facts that create a reasonable inference that the IRB Mandate does not serve a legitimate pedagogical purpose. For instance, Ms. Issak alleges the IRB Mandate exists separate and apart from the academic requirements for obtaining a PhD and that Ms. Issak's Doctoral Committee has already approved her research. *See* ECF34 ¶¶48–49 (alleging Plaintiff's advisor and Doctoral Committee approved her dissertation). Plaintiff also alleges that it is the Doctoral Committee, and not the IRB, which possesses the relevant academic expertise to assess the validity of her research. *See* ECF34 ¶¶50–53 (listing members of Plaintiff's Doctoral Committee and how their expertise matches her dissertation topic). This case therefore differs from the Ninth Circuit's decision Defendants cite in *Brown v. Li*, 308 F.3d 939 (9th Cir. 2002), wherein the court held that it served a "legitimate pedagogical purpose" for a thesis committee to refuse to approve a thesis that included a "Disacknowledgment" section denigrating university officials.

Given the selective application of the IRB Mandate to communicative research depending on whether it seeks to contribute to generalizable knowledge or not, discovery is needed to assess whether Defendants hold a legitimate pedagogical concern and whether the IRB Mandate is reasonably related to any such concern. None of the cases Defendants cite establish their claimed pedagogical concerns trump Ms. Issak's First Amendment rights, particularly at the Motion to Dismiss stage.

D. Whether the IRB Mandate Satisfies Strict Scrutiny—Or Even Intermediate Scrutiny—Should Not Be Decided at the Motion to Dismiss Stage

Because the IRB Mandate represents a content, speaker, and viewpoint-based regulation, it is "presumptively unconstitutional and may be justified only if the government proves that [it is] narrowly tailored to serve compelling state interests." *Reed*, 576 U.S. at 163. And "[w]hen the Government restricts speech, the Government bears the burden of proving the constitutionality of its actions." *United States v. Playboy Enter. Grp., Inc.*, 529 U.S. 803, 816 (2000).

The government cannot satisfy its burden by merely declaring a generalized governmental interest or speculating about a potential harm. *See Consol. Edison Co. of N.Y. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 530, 543 (1980); *Libertarian Party of Ohio v. Blackwell*, 462 F.3d 579, 593 (6th Cir. 2006). Yet, Defendants offer only generalized governmental interests to justify the IRB Mandate and speculate that communicative research poses a risk to individuals who willingly speak with anthropologists. Specifically, Defendants posit the IRB Mandate is necessary to protect "human research subjects" and the "unique rights of foreign research subjects," and to teach students how to "respect … the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University."[14] ECF41 at 15–16 (cleaned up). These asserted interests do not justify dismissal of Ms. Issak's Amended Complaint.

First, it is axiomatic that the government cannot limit speech under the convenient guise of protecting individuals from that speech. *See Brown v. Ent. Merchs. Ass'n*, 564 U.S. 786, 791 (2011) ("new categories of unprotected speech may not be added to the list by a legislature that concludes certain speech is too harmful to be tolerated"). Thus, Defendants cannot rely on a harm supposedly flowing from culturally inappropriate speech. Second, Defendants must show that the problem the government allegedly aims to address actually exists. *See Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993) (declaring that a party's burden of justifying a speech restriction, even on commercial speech, "is not satisfied by mere speculation or conjecture"). While Defendants identify the horrors of Nazi experimentation and the Tuskegee syphilis study to justify the IRB Mandate, "[a] court applying strict scrutiny must ensure that a compelling interest supports *each application* of a statute restricting speech." *FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 478 (2007). Thus, even assuming the problems from Nazi Germany and unethical experimentation on syphilis sufficed to show research subjects still risk abuse and injury from medical experimentation, that would not establish there is any actual problem with voluntary participation in short-term communicative research such as Ms. Issak seeks to undertake. (The Nazi and Tuskegee experiments were government research, not private; they were without consent or at least without informed consent; they involved physical contact, not just speech.) Further,

[14] Defendants present a third governmental interest, namely, that applying the IRB Mandate to Ms. Issak's research serves the purpose of preserving federal funding. ECF41 at 35. Here, Defendants reason that because the University committed in its federal-wide assurance or FWA application to "apply[ing] the ethical principles of the Belmont Report to all UT-funded research projects," ECF41 at 41, there is an important governmental interest in applying the IRB Mandate to non-federally funded research. ECF41 at 35. But Defendants voluntarily imposed the IRB Mandate on communicative research not funded by the federal government. It is circular to argue that the need to comply with the standards Defendants voluntarily adopted justifies complying with those standards.

Defendants offer no evidence that IRBs actually protect research subjects, nor could they: In 2023, the Government Accountability Office found federal agencies have yet to assess whether "IRB reviews are effective in protecting human subjects," even for medical or pharmaceutical research.[15]

E. The IRB Mandate's Content-Based Restriction Is Unrelated to the Proffered Government Interest and Thus Cannot Withstand Scrutiny

Defendants' acknowledgement that Ms. "Issak could ask the *same* questions to the *same* participants and acquire the *same* answers without undergoing IRB review if those answers were to be used as part of a 'biography or oral history,'" ECF41 at 39, proves fatal to any argument that the IRB Mandate protects research subjects. The IRB Mandate's distinction between research designed to produce generalizable versus non-generalizable knowledge "has nothing to do with" the government's interest in protecting research subjects. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 424 (1993) (quoting *Simon & Schuster, Inc. v. Members of the N.Y. State Crime Victims Bd.*, 502 U.S. 105, 120 (1991)). Said otherwise, the IRB Mandate, when applied to communicative research in the social sciences, lacks any congruence with any asserted governmental interest. In fact, Defendants do not even attempt to justify their decision for the disparate treatment, instead pointing solely to a passing line in the federal register to suggest that the federal government believed ethical rules governing oral historians and journalists protected the human subjects interviewed from harm caused by the publication of research. ECF41 at 13. There is no evidence that the Defendants in this case justified the differing standards for oral historians and journalists and anthropologists based on ethical rules, much less is there evidence showing why the ethical rules that apply to anthropologists wouldn't similarly suffice—so the government's justification has no basis in fact.[16]

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[15] *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness*, U.S. GOV'T ACCOUNTABILITY OFFICE (Feb. 16, 2023), https://www.gao.gov/products/gao-23-104721.

[16] *See Anthropological Ethics*, AMERICAN ANTHROPOLOGICAL ASSOCIATION, https://americananthro.org/about/anthropological-ethics/ (last visited Sept. 29, 2025).

The Supreme Court has long struck regulations of speech where the government had justified the restriction based on a purported government interest that was mismatched with the statute. Said otherwise, when a regulation adopts a content-based distinction that "has nothing to do with" the government's proffered interest, it cannot survive strict scrutiny. *Discovery Network, Inc.*, 507 U.S. at 424. Thus, in *Watchtower Bible & Tract Society of New York v. Village of Stratton*, 536 U.S. 150 (2002), the Supreme Court struck a municipality's licensing requirement for door-to-door solicitation, where the government claimed an interest in protecting privacy and preventing crime. *Id.* at 168. The Court refused to accept either asserted justification because there was "an absence of any evidence of a special crime problem related to door-to-door solicitation." *Id.* at 169. The Supreme Court further held a resident's privacy already received "ample protection" from "the resident's unquestioned right to refuse to engage in conversation." *Id.* at 168; *see also Sorrell*, 564 U.S. at 575. The same reasoning applies to individuals researchers seek to interview: Just as the residents in *Watchtower Bible* could protect themselves by refusing to speak with the Jehovah's Witnesses approaching their homes, so can the women whom Ms. Issak may approach in public places. *Cf.* 80 Fed. Reg. 53,933, 53,951–52 ("[A]ll individuals, including vulnerable populations, would understand that actively providing response to ... surveys, or interview procedures constitutes consent to participate and that the risk associated with such participation would be related to disclosure of the information they provided.").

Similarly, in *Carey v. Brown*, 447 U.S. 455 (1980), the Supreme Court recognized the government held an interest in protecting privacy but nonetheless struck a ban that prohibited residential picketing because it illogically allowed labor picketing. *Id.* at 467–69. The Court reasoned that the law could not pass constitutional muster because "nothing in the content-based labor-nonlabor distinction has any bearing whatsoever on privacy." *Id.* at 465. Likewise, in *Discovery Network*, the Court acknowledged a city's interest in reducing the number of newsracks for aesthetic purposes, but it invalidated an ordinance that prohibited only commercial newsracks. 507 U.S. at 424–25. Because commercial and noncommercial newsracks would have been "equally at fault," *id.* at 426, the Supreme Court held the city's distinction had "no relationship whatsoever to [its] interests," and therefore could not pass strict scrutiny. *Id.* at 424. For the same reason, the Supreme Court in *Simon & Schuster*, 502 U.S. at 120, held that a law which distinguished between income derived from a criminal's descriptions of his crimes and other sources could not pass constitutional muster because the distinction had "nothing to do with" the government's interest in transferring proceeds of crimes from criminals to victims.

Finally, in *Florida Star v. B.J.F.*, 491 U.S. 524, 526 (1989), the Supreme Court invalidated a ban on disseminating the name of sexual assault victims through "any instrument of mass communication," holding that by limiting the ban to "mass communication," the state did not address other means of spreading a victim's name. *Id.* at 540. This underinclusiveness "rais[ed] serious doubts about whether [the state was], in fact, serving," its claimed interests. *Id.* An individual could have, for example, "maliciously spread[] word" of a victim's identity to her neighbors and co-workers. *Id.* This was so, even though such "backyard gossip" would have been just "as devastating as the exposure of her name to large numbers of strangers." *Id.* Accordingly, as the Court could not "conclude that [the State's] selective ban on publication by the mass media satisfactorily accomplishe[d] its stated purpose," it held the law failed scrutiny under the First Amendment. *Id.* at 541. *See also Cent. Radio Co. v. City of Norfolk*, 811 F.3d 625, 634 (4th Cir. 2016) (rejecting the city's argument that limiting the size of secular flags was necessary to "eliminate threats to traffic safety" because there was "no evidence in the record that secular flags were any more distracting than religious ones").

Defendants' argument that the IRB Mandate protects human subjects and teaches students how to conduct ethical research runs headlong into this precedent because the generalizable/non-generalizable distinction the IRB Mandate adopts has no connection to the purported governmental interest. The fact that a researcher could ask *any* question of *any* individual—including asking questions the IRB considers potentially harmful, to individuals the IRB considers vulnerable—so long as the researcher does not draw generalizable conclusions from those conversations, establishes the IRB Mandate does not actually further the government's stated interests. Relatedly, because the IRB Mandate does not address Defendants' claimed interests, it is not narrowly tailored. *See e.g.*, *Discovery Network*, 407 U.S. at 430. In short, because the potential risk from communicative research has nothing to do with whether the researcher will draw generalizable conclusions, the IRB Mandate cannot survive strict scrutiny.[17]

F. The IRB Mandate Constitutes an Unconstitutional Prior Restraint of Speech

Defendants acknowledge that when "*speech* is conditioned upon the prior approval of public officials," a prior restraint exists, ECF41 at 32, but claim that "[t]he challenged IRB requirements are a far cry from an unconstitutional prior restraint." *Id.* at 33. Defendants, however, merely repeat their flawed conclusion that the IRB Mandate "targets conduct, not speech," and that "[i]t follows that the challenged requirements are 'not a prior restraint.'" *Id.* That argument fails as shown above. *See supra* at 14–21.

Moreover, the allegations, read in the light most favorable to Ms. Issak—as they must be under Rule 12(b)(6)—plausibly state a claim that the IRB Mandate delegates the IRB unconstitutional, unconstrained discretion. ECF34 ¶207. "[A] law subjecting the exercise of First Amendment freedoms to the prior restraint of a license must contain narrow, objective, and definite standards to guide the licensing authority." *Forsyth Cnty. v. Nationalist Movement*, 505 U.S. 123, 131 (1992) (cleaned up). And

[17] Defendants fail to analyze the IRB Mandate under the strict scrutiny standard, instead focusing solely on the inapplicable intermediate scrutiny standard that controls the regulation of conduct that incidentally burdens speech. ECF41 at 31–32. Nonetheless, Defendants declare that "even if this Court considers heightened scrutiny, the challenged IRB requirements do not violate Issak's First Amendment rights." ECF41 at 31. *See also id.* at 35 (declaring the IRB Mandate "is narrowly targeted to further a compelling state interest"). Neither Defendants' conclusory declaration that the IRB Mandate satisfies strict scrutiny nor its analysis of intermediate scrutiny justify dismissal of Ms. Issak's complaint. To the contrary, for the same reasons Defendants cannot succeed on their Motion to Dismiss under strict scrutiny, their motion fails even under the more lenient intermediate standard that requires an "important governmental interest."

thus, a restriction that "makes the peaceful enjoyment of freedoms which the Constitution guarantees contingent upon the uncontrolled will of an official—as by requiring a permit or license which may be granted or withheld in the discretion of such official—is an unconstitutional censorship or prior restraint upon the enjoyment of those freedoms." *Staub*, 355 U.S. at 322.

Such is the case here. In deciding whether to approve Ms. Issak's research, Defendants must make numerous judgments that involve significant and unfettered discretion, such as determining the "importance of the knowledge that may reasonably be expected to result" and if the "[r]isks to the subjects" from interviews "are reasonable in relation to the anticipated benefits" to the people being interviewed.[18] That "depends upon prevailing community standards and subjective determinations of risk and benefit."[19] Moreover, the IRB partially outsources its discretion to non-citizens by requiring applicants to obtain letters of "cultural appropriateness" from a local authority.

These assessments involve the appraisal of facts, exercise of judgment, formation of an opinion, and are impermissibly subjective. This is just the sort of discretion that concerned the Court in *Forsyth*—the type of discretion that could be used to "suppress[] a particular point of view." 505 U.S. at 130 (cleaned up). Depending on its point of view, an IRB could decide a particular piece of knowledge is or is not important. Such "subjective determinations" are "a virtual prescription for unconstitutional decision making." *Child Evangelism Fellowship of S.C. v. Anderson Sch. Dist.*, 470 F.3d 1062, 1070 (4th Cir. 2006). Accordingly, the Amended Complaint plausibly alleges the IRB Mandate establishes a prior restraint lacking in the constitutionally required definitive standards.

G. The IRB Mandate Imposes an Unconstitutional Condition to Ms. Issak Obtaining Her PhD

[18] ECF34 ¶145 (quoting *Full Board Review*, Research Integrity & Assurance, UNIV. OF TENN., https://research.utk.edu/research-integrity/full-board-review/ (last visited Sept. 29, 2025)).
[19] *Institutional Review Board Guidebook, Ch. III: Basic IRB Review*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://biotech.law.lsu.edu/research/fed/ohrp/gb/irb_chapter3.htm.

Recognizing that "constitutional violations may arise from the deterrent, or 'chilling,' effect of governmental [efforts] that fall short of a direct prohibition against the exercise of First Amendment rights," *Laird*, 408 U.S. at 11, the Supreme Court's modern "unconstitutional conditions" doctrine holds that the government "may not deny a benefit to a person on a basis that infringes [her] constitutionally protected ... freedom of speech," *Perry v. Sindermann*, 408 U.S. 593, 597 (1972), even if there is no entitlement to that benefit. Yet, Defendants require Ms. Issak to submit to their unconstitutional IRB Mandate to complete the communicative research needed to write her already approved dissertation. Defendants' IRB Mandate thus constitutes as an unconstitutional condition preventing Ms. Issak from obtaining a PhD.

Defendants argue that because Ms. Issak remains free to conduct research separate from her PhD program, there is no unconstitutional condition. ECF41 at 44. This argument misses the point: Ms. Issak's unconstitutional condition claims are based on Defendants' refusal to allow her to undertake communicative research *for her PhD* unless she submits to the IRB Mandate. So, it is no answer to say that Ms. Issak can undertake the same research, just not to obtain her PhD.

Nor do *Rust v. Sullivan*, 500 U.S. 173, 197 (1991) or *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 912 (6th Cir. 2019), support Defendants' argument. Those cases both involved challenges to government funding programs. The Supreme Court made clear that when the government funds a program, it can, without violating the constitution, "encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way." *Rust*, 500 U.S. at 193. Conversely, the government cannot condition funding on a grantee abandoning speech rights "outside the scope of the [government-]funded program." *Id.*

That principle does not apply when the plaintiff's challenge is unconnected to a funding decision. Even *Rust* recognized as much, explaining "[t]here is a basic difference between direct state interference with a protected activity and state encouragement of an alternative activity consonant with legislative policy." *Id.* at 197. Thus, that Ms. Issak remains free to conduct research separate from her PhD program is irrelevant because she is *not* challenging a funding decision. Instead, what matters is that Defendants prevent Ms. Issak from obtaining her PhD unless she abandons her First Amendment rights and submits her dissertation to the IRB Mandate's speech restraints. Ms. Issak has thus plausibly alleged the IRB Mandate constitutes an unconstitutional condition. ECF34 ¶¶150–52.

III. MS. ISSAK ALLEGED MULTIPLE CLEARLY ESTABLISHED FIRST AMENDMENT CLAIMS AND ANY DECISION ON QUALIFIED IMMUNITY MUST AWAIT SUMMARY JUDGMENT

Defendants here cannot hide behind qualified immunity because the IRB Mandate violates clearly established First Amendment rights: Qualified immunity does not apply when government officials violate a plaintiff's clearly established constitutional rights. *Ashcroft v. al-Kidd*, 563 U.S. 731, 735 (2011) (citation omitted). As detailed above, Ms. Issak has plausibly alleged the IRB Mandate abridges her First Amendment rights in multiple ways, and each theory on which Ms. Issak relies has long been clearly established. Accordingly, the Individual-Capacity Defendants' affirmative defense of qualified immunity fails. *See Barton v. Neeley*, 114 F.4th 581, 592–93 (6th Cir. 2024) (lower court properly denied Defendant's Motion to Dismiss First Amendment claim based on qualified immunity because the law was clearly established).

Specifically, it has long been clearly established that prior restraints on speech are unconstitutional. *See Staub*, 355 U.S. at 322. The Sixth Circuit in *McGlone v. Bell*, 681 F.3d 718, 733–34 (6th Cir. 2012), also made clear that principle applies in the university setting. *See id.* at 735 (holding a university's requirement that individuals not affiliated with the university needed to apply to speak on campus violated plaintiff's clearly established First Amendment rights). Further, it has long been clearly established that "a law subjecting the exercise of First Amendment freedoms to the prior restraint of a license must contain narrow, objective, and definite standards to guide the licensing authority." *Forsyth*, 505 U.S. at 131 (quotations and citations omitted).

It has also long been established that content, speaker, and viewpoint-based restrictions on speech are subject to strict scrutiny and rarely pass constitutional muster. *See Reed*, 576 U.S. at 168–70; *Bible Believers*, 805 F.3d at 248 . It has been clearly established for nearly three decades that a regulation discriminating between "general" and "specialized" speech constitutes an unconstitutional content-based law. *Ragland*, 481 U.S. at 228–31. Relatedly, since at least 2010, it has been clearly established that a regulation governs "speech" and not "conduct," if what "trigger[s] coverage" is the communicative message. *Holder*, 561 U.S. at 28.

Moreover, it has long been understood that "state colleges and universities are not enclaves immune from the sweep of the First Amendment." *Healy v. James*, 408 U.S. 169, 180 (1972). Neither students nor teachers "shed their constitutional rights to freedom of speech or expression at the schoolhouse gate." *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 (1969). Accordingly, that Defendants violated Ms. Issak's First Amendment rights in the context of speech undertaken to complete her dissertation is of no moment. Further, the unconstitutional condition doctrine has long been clearly established, holding "[t]he government may not deny an individual a benefit, even one an individual has no entitlement to, on a basis that infringes his constitutional rights." *Hodges*, 917 F.3d at 911 (citing *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013)).

Notwithstanding the clarity of this First Amendment jurisprudence, the Individual-Capacity Defendants insist they are entitled to qualified immunity, seemingly arguing that because "no academic or university had challenged the constitutionality of IRB review in court," ECF41 at 20, a reasonable school official would not be on notice of the unconstitutionality of their conduct.

Defendants are wrong. "Although clearly established law cannot be defined 'at a high level of generality,' a case with near-identical facts need not exist for a right to be clearly established." *Barton*, 114 F.4th at 591 (citations omitted). Indeed, the Supreme Court has explicitly stated that "officials can still be on notice that their conduct violates established law even in novel factual circumstances." *Hope* *v. Pelzer*, 536 U.S. 730, 741 (2002). The Sixth Circuit has likewise held that it does "not require a prior, precise situation, a finding that the very action in question has previously been held unlawful, or a case directly on point." *Guertin v. Michigan*, 912 F.3d 907, 932 (6th Cir. 2019) (quotations and citations omitted). *See also Lyons v. City of Xenia*, 417 F.3d 565, 579 (6th Cir. 2005) (explaining caselaw need not squarely govern an issue for a right to be clearly established).

The Sixth Circuit in *Guertin* further explained that "an action's unlawfulness can be clearly established from direct holdings, from specific examples describing certain conduct as prohibited, or from the general reasoning that a court employs." *Guertin*, 912 F.3d at 932 (cleaned up). The Court's application of those principles in *Guertin* is instructive. In *Guertin*, plaintiffs who were injured by the lead contamination of the Flint, Michigan water supply sued various government officials who allegedly bore responsibility for the injuries. *Id.* at 915. Defendants moved to dismiss based on qualified immunity. *Id.* On appeal, the Sixth Circuit held defendants whom plaintiffs had plausibly alleged were deliberately indifferent to their right to "bodily integrity" were not entitled to qualified immunity on the substantive due process claims. *Id.* at 928. The Court reasoned that there was a long line of due-process case law clearly establishing that "an individual's right to bodily integrity is sacred, founded upon informed consent, and may be invaded only upon a showing of a government interest." *Id*. at 934. *Guertin* reached that conclusion even though the "long line" of due-process cases involved very different facts from those facing the court in the Flint water crisis case. Yet, the Sixth Circuit held the reasoning of those cases was sufficient to put the state officials on notice of controlling constitutional principles. *Id*. at 933-34.

The Sixth Circuit in *Guertin* relied heavily on *In re Cincinnati Radiation Litigation*, 874 F. Supp. 796 (S.D. Ohio 1995), finding that case "especially analogous," *Guertin*, 912 F.3d at 921, which might seem strange if only the facts of the two cases were considered. Afterall, the Flint water crisis involved residents injured after government officials changed the city's water source and then failed to properly treat the water, subjecting homeowners to the toxins in the water, while in *Cincinnati Radiation*, University of Cincinnati researchers "subjected cancer patients to radiation doses consistent with those expected to be inflicted upon military personnel during a nuclear war." *Guertin*, 912 F.3d at 921 (citing *Cincinnati*, 874 F. Supp. at 802–04). The researchers did not "disclose the risks associated with the massive radiation doses or obtain consent to irradiate the patients at those levels for those purposes—they instead told the patients that the radiation was treatment for their cancer." *Id.* (citing *Cincinnati*, 874 Supp. at 803–04).[20]

Notwithstanding that the facts in *Guertin* and *Cincinnati Radiation* differed greatly, the Sixth Circuit held the plaintiffs' right to bodily integrity was clearly established because both involved "individuals engaged in voluntary actions that they believed would sustain life, and instead [they] received substances detrimental to their health." *Id.* And both cases involved "government officials engaged in conduct designed to deceive the scope of the bodily invasion" and "grievous harm occurred." *Id.*

Under *Guertin*, then, it is irrelevant that the First Amendment principles on which Ms. Issak relies arose in differing factual scenarios. Instead, what matters is that the same core First Amendment principles were clearly established—and they were. Accordingly, the Individual-Capacity Defendants' Motion to Dismiss based on qualified immunity should be denied.

Alternatively, this Court should withhold judgment on qualified immunity pending discovery, for the Sixth Circuit has made clear "that granting qualified immunity at the motion to dismiss stage is usually disfavored." *Marvaso v. Sanchez*, 971 F.3d 599, 605 (6th Cir. 2020). *See also Wesley v. Campbell*, 779 F.3d 421, 433 (6th Cir. 2015) (explaining "it is generally inappropriate for a district court to grant a 12(b)(6) motion to dismiss on the basis of qualified immunity"). Rather, the appropriate time for

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[20] Like the syphilis study undertaken in Tuskegee, the Cincinnati radiation experimentation was conducted at the behest of the federal government and involved medical research.

consideration of this defense is following discovery because "[a]bsent any factual development beyond the allegations in a complaint, a court cannot fairly tell whether a case is 'obvious' or 'squarely govern[ed]' by precedent[.]" *Evans-Marshall v. Bd. of Educ. of Tipp City Exempted Vill. Sch. Dist.*, 428 F.3d 223, 235 (6th Cir. 2005) (Sutton, J., concurring). *See also Diei*, 116 F.4th at 648 (reasoning that summary judgment is a more appropriate time to determine qualified immunity "given the record development that typically occurs during discovery"); *Anders v. Cuevas*, 984 F.3d 1166, 1175 (6th Cir. 2021) ("[I]t is often perilous to resolve a Rule 12(b)(6) motion on qualified immunity grounds because development of the factual record is frequently necessary to decide whether the official's actions violated clearly established law.") (quotations omitted). That is because qualified immunity involves a fact-intensive determination—and that is "especially so in the First Amendment context." *Diei*, 116 F.4th at 650–51 (citation omitted). *See also McGlone*, 681 F.3d at 728 ("A motion to dismiss for failure to state a claim is disfavored, especially when one's civil rights are at stake."). Even if the Court disagrees that Ms. Issak's First Amendment rights were clearly established, at a minimum, the Court should withhold judgment on qualified immunity pending discovery.

CONCLUSION

As established above, Ms. Issak's Amended Complaint alleged multiple plausible First Amendment claims. Accordingly, Defendants' Motion to Dismiss should be denied in its entirety.

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CERTIFICATE OF SERVICE

On September 30, 2025, I electronically submitted this document to the clerk of the court of the U.S. District Court for the Eastern District of Tennessee using the court's electronic case filing system. I certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/*Margot Cleveland*