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Race, Place, and The Federal Exception from Informed Consent (EFIC): A Semiotic Approach

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ABSTRACT OF THE DISSERTATION

Race, Place, and The Federal Exception from Informed Consent (EFIC): A Semiotic Approach

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The Exception from Informed Consent (EFIC) regulatory mechanism can be used to waive federal informed consent requirements for emergency medical research, pending satisfaction of pre-trial requirements. EFIC's most notoriously challenging pre-trial requirement is 'community consultation,' a process through which EFIC researchers solicit public feedback on their trials. Using a Peircean semiotic framework, this thesis unpacks the presuppositions undergirding the idea that community consultation can reduce friction between emergency clinical trials carried out without informed consent and the values of patients enrolled in them. I introduce a semiotics of prediction, showing how assumptions about race figure prominently in the commensuration-based tasks of selecting community consultation respondents and subsequently generalizing findings from these respondents to broader populations. I suggest that in practice the content and / or generalizability of feedback collected through community consultation has very limited utility for reducing friction. Rather, community consultation's primary function—as it is currently operationalized—is one of public relations, whereby the discursive processes through which community feedback is solicited have more bearing on EFIC trials' public acceptability

than the content of community feedback and the ability of biomedical research actors to transpose this content across contexts. By examining who participates in / is affected by the discursive processes through which community feedback is solicited, I help explain otherwise untheorized yet nonetheless troubling disparities between the acceptability of EFIC as determined by community consultation respondents and the acceptability of EFIC as determined by EFIC trial participants and their surrogates.

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Table of Contents

Introduction

"—barbershops. Um, hair salons?" A member of the institutional review board (IRB) responsible for overseeing the clinical trial on which I am a collaborator suggests that we—the trial team—connect with local leaders of these businesses in order to coordinate a series of pre-trial focus groups with their customers. Another member of the IRB pipes up, "How about churches in West Philly?" She suggests that we reach out to pastors, in the hopes that they will help us reach their congregants. Although perhaps seemingly unrelated at first glance, these recruitment site suggestions—West Philadelphian barbershops, hair salons, and churches—are categorically similar: to university affiliates, they are hubs of Black social life in Philadelphia.

The association of Black social life with barbershops, hair salons, and churches is neither endemic to the imaginations of the regulatory actors who oversee our clinical trial nor Philadelphia. Rather, this trope is visible in media from a range of disciplines (e.g., African American studies, photography) examining Black social life across the United States.[1,2] One specific interest of scholars of Black social life is the way in which barbershops, hair salons, and churches function as Black healthcare institutions.[1] Studies have found that barbershops serving Black men offer a critical space for discussion of familial health matters and that they can and sometimes do serve as links to healthcare resources such as hypertension screening, HIV / AIDS support, and physical activity education.[1,3–5]

Unlike the association between Black social life and barbershops, hair salons, and churches, the association between Black social life and 'West Philly' is more endemic to the local imagination. That West Philadelphia remains predominantly Black is not merely a fact of demographic and geographic interest. Rather, within the discursive networks of the academic medical site at which

my team and I are based, West Philadelphia has come to be defined by and valuated on the basis of its concentration of Black constituents. That is to say, to us university affiliates, this section of the city is not simply statistically black, but iconically (and sometimes usefully) black.

Identifying barbershops, hair salons, and churches in West Philadelphia as local hubs of Black social life, and more specifically Black healthcare, biomedical actors in Philadelphia frequently solicit assistance from these establishments for matters ranging from minority public health promotion to minority research subject recruitment. Recently on the public health front, for example, partnerships between a major Philadelphia-based academic medical center, the University of Pennsylvania Health System, and barbershops, hair salons, and churches played a critical role in decreasing racial disparities in local COVID-19 vaccine uptake. On the research front, scientists from West Philadelphia's academic medical centers often reach out to barbershops, hair salons, and churches with interests in collecting data from customers and congregants. Yet, per the leaders of these establishments, such scientists very rarely reciprocate. That is, they do not deliver resources that address customers' and congregants' most pressing needs, such as affordable, quality housing and safer streets. The continual extraction of data and infrequent provision of relevant resources has complicated relations between West Philadelphia's academic medical centers and Black West Philadelphians.

As my team and I listen and take note of the IRB's suggestions, the legacy of Black establishments as a valuable tool for the very biomedical institutions that so frequently fail them spurs concerns about what the IRB is asking us to do. Will partnering with leaders from West Philadelphia's barbershops, hair salons, and churches help us ensure that our clinical trial respects the values of patients enrolled in the trial? Or will such partnerships merely help us to check a regulatory box needed for approval of our clinical trial, without attending to the ways in

which the trial aligns with the values of enrolled patients? As our meeting with the IRB wears on, we sit uneasily with the knowledge that we are expected to connect with iconically Black establishments to host pre-trial focus groups, despite our own doubts about our capacity to use the feedback obtained through these focus groups to ensure that the trial aligns with participants' values. Given that I am the one who will be responsible for coordinating and facilitating these focus groups, I am especially apprehensive during this meeting. As the primary research coordinator and in-house social scientist for my team's clinical trial, I am constantly torn between executing bureaucratic processes needed to facilitate the trial's approval and analyzing these processes in a way which—unfortunately—tends to reveal dimensions of them that present ethical concern.

The clinical trial on which I collaborate compares two treatments for in-hospital cardiac arrest (IHCA), the technical term for when a patient's heart stops in the hospital. Because IHCA renders patients incapacitated and because the success of resuscitation efforts hinges in-part on the immediacy of intervention, obtaining informed consent from patients or their surrogates for participation in interventional IHCA trials is virtually impossible. Thus, our clinical trial uses the Exception from Informed Consent (EFIC) regulatory mechanism to waive the federal informed consent requirements ordinarily applicable to research. EFIC allows us to enroll patients in our trial without informed consent, once we have satisfied the regulatory mechanism's pre-trial requirements.[6]

EFIC's most notoriously challenging pre-trial requirement is "consultation with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn."[6] Colloquially, this series of engagements through which scientists solicit public feedback about their trials is called 'community consultation.'[7] Investigators are supposed

to leverage this feedback to ensure that their trials are relatively respectful of the values of patients who will ultimately be enrolled. To do so, investigators might modify their scientific procedures in response to community consultation feedback, for example. Once they have considered the feedback secured through community consultation, the feedback and (potentially revised) clinical protocol are reviewed by the IRB. The Food and Drug Administration (FDA) "expects the IRB to consider the concerns and objections raised during community consultation activities when the IRB deliberates on whether to approve, require modifications [to] . . . or disapprove the research activity" for which the scientific team seeks review under EFIC.[7]

EFIC raises challenging ethical questions as a regulatory mechanism that imposes exigent demands on already-strained clinician scientists who seek to waive informed consent for enrollment in their clinical trials—consent arguably being the most fundamental tenet of biomedical research ethics in the United States. Given the substantial demands for resource investment incurred by community consultation and community consultation's position as a tool for securing the ethical legitimacy of research in the absence of consent, questions about the ethical utility of community consultation are of particular importance. Since EFIC's establishment in 1996, bioethicists, regulators, and clinician scientists have contemplated this utility.[8–11] Most of their efforts, however, have been theoretically oriented—detached from the empirics of community consultation. This detachment may help explain why much of the utility they identified for community consultation appears unrealized. For example, one role for community consultation—widely recognized across literature that theorizes EFIC—is to enhance protections for trial participants by helping investigators identify and subsequently address otherwise unapparent risks of the research.[8,11] Yet, my team and others have found that EFIC investigators rarely modify their trials in response to community feedback,[10] and follow-up

interviews with patients and the surrogates of patients enrolled in EFIC trials find that a sizeable percentage of this population disapproves of having been enrolled in a clinical trial without giving consent.[12] These findings suggest that community consultation is not effectively cultivating enhanced protections for trial participants. Setting realistic expectations for what community consultation should achieve requires empirical investigation of community consultation's utility in practice.

To better understand misalignments between community consultation's empirical utility and the utility bioethicists, regulators, and clinician scientists aspire to for it, this thesis draws on two data sets: 1) a series of interviews I conducted, focused on the community consultation experiences of clinician scientists recruited from a breadth of EFIC trials and EFIC trial sites across the United States, and 2) my experience, accounted ethnographically, leading community consultation efforts for an EFIC trial sited at an academic medical center in Philadelphia, Pennsylvania. (A brief terminological note: Throughout the duration of this thesis, I will refer to the EFIC clinician-scientists I interviewed as 'interviewees.' Though I used interview methods at times when conducting community consultation with clinicians, patients, and patients' families, for sake of clarity I will refer all who interviewed (or participated in focus groups) as part of community consultation as 'respondents.' I will use the term 'participant' to refer to patients who will be / are enrolled in EFIC trials.)

Using a Peircean semiotic framework, this thesis unpacks the presuppositions undergirding the idea that community consultation can reduce friction between emergency clinical trials carried out without informed consent and the values of patients enrolled in them. Here, I introduce a semiotics of prediction, showing how assumptions about race figure prominently in the commensuration-based tasks of selecting community consultation respondents and subsequently

generalizing findings from these respondents to broader populations. I ask: Why are barbershops, hair salons, and churches in West Philadelphia the right places to recruit from to accomplish community consultation's goal of reducing friction between emergency clinical trials carried out without informed consent and the values of patients enrolled in them? And, why are focus groups so vital to this goal? More synthetically, what is the power of combining focus groups as a data collection method with recruitment from sites iconic of Black social life? I suggest that in practice the content and / or generalizability of feedback collected through community consultation has very limited utility for reducing friction. Rather, community consultation's primary function—as it is currently operationalized—is one of public relations, whereby the discursive processes through which community feedback is solicited have more bearing on EFIC trials' public acceptability than the content of community feedback and the ability of biomedical research actors to transpose this content across contexts. By examining who participates in / is affected by the discursive processes through which community feedback is solicited, I help explain otherwise untheorized yet nonetheless troubling disparities between the acceptability of EFIC as determined by community consultation respondents and the acceptability of EFIC as determined by EFIC trial participants and their surrogates.

Conducting Community Consultation Interviews: An Autoethnographic Account

"But what will focus groups tell us regarding public opinions about the trial that our interviews won't?" I ask one of my team members following a meeting with the IRB. The IRB has determined that the 120 one-to-three-hour(s)-long, in-depth, semi-structured interviews we've collected from clinicians, patients, and family members of patients at our academic medical center are not sufficient to satisfy the community consultation pre-trial requirement that stands

between us and approval of our clinical trial under EFIC. As the one who conducted all our interviews, I'm frustrated.

Our interviews covered a range of topics, touching on (and going beyond) the swath typical for community consultation. We asked about: preferences for medical decision making, experience with cardiac arrest, experience with and opinions on the academic medical center / soon-to-be trial site at which we are based, experience with participation in clinical research, opinions on emergency medical research and our clinical trial more specifically, social networks, and community life. Conducted in our intensive care units, surgical areas, waiting rooms, and medical floors from April 2020 through August 2021, these interviews bear witness to the trauma of hospital life amid a global pandemic. While our community consultation interviews were in no way intended to be about COVID-19, they were filtered through it, colored by it. Perhaps, I think—as I attempt to work through my frustration with the IRB's determination—I am sentimental about the sufficiency of these interviews in-part because of it.

Our interviews with clinicians capture their fear and exhaustion as they were tasked with carrying on caring as normal whilst they themselves were uncared for, subjected to unprecedentedly hostile biological and social conditions. The clinician interviews tell tales of viral contagion, racism, and not enough sick days. They tell tales of limited support making decisions about patient care, limited supplies, and limited assistance carrying out independently-made decisions with limited supplies. Allocating beds and lifesaving machinery when there wasn't enough to go around. Slipping disks from proning patients without assistance. Months spent quarantining from family members after being drafted to work the COVID unit. As I tried to focus the interviews on decision making for emergency medical research to ensure adherence to community consultation standards, it became increasingly apparent that making clinical

decisions about how to provide care for a largely unfamiliar disease (i.e., Covid) under duress (a term that defines the entirety of the healthcare delivery experience from 2020 onward) was a critical reference point for my respondents. It is this reference point to which opinions about our clinical trial are most strongly calibrated. As the clinician interviews progressed later into the pandemic, therapy and hopelessness and the exasperation of waiting for viral and social cures were mentioned with increasing frequency. Some of the clinicians I was due to interview quit—in what others described as attempts to preserve dignity—before I had the opportunity to interview them.

The patient interviews, too, are rife with desperation, exhaustion, and hopelessness. These interviews capture the loneliness of patients who spent months in windowless intensive care units. Some of these patients were sick with COVID, prognosed dismally by media outlets when staff came by to click on the patients' TVs for them. (Many of the patients were too sick to click on the TVs themselves). When I spoke to these patients, it was sometimes as though they had come to believe that they were supposed to die. These interviews capture interruptions between providers and patients, terse and strained from pain that the pharmacy at times refused to treat. The pharmacy wanted to refrain from being an accomplice to addiction, it was explained to me. And I am sure the pharmacy was legally obliged to do so. But during the pained breaths and pauses in my interviews with patients, I silently questioned the sensibility of avoiding addiction. What does addiction matter if the world is ending? It felt like it was. The patient interviews unintentionally trace the development and dispersion of vaccines. As vaccination became more widespread among hospital personnel, they came into patient rooms with increasing frequency. Hospital personnel can be heard in my audio recordings with patients, occasionally interjecting questions about the interview process while checking patient vitals. When vaccination first

reached the public, a cocktail of desire for it and uncertainty about it flowed into the interviews. Disparities in early access to the vaccine, too, are etched into the historic record that our community consultation effort became. As the vaccine became more widely accessible, we saw uncertainty as to whether illness was caused by vaccination. Patients openly question whether their heart failure and brain tumors were attributable to it. In such ways, the interviews capture distrust of the government and healthcare systems. They show with uncanny clarity how experiences with these institutions mediate views about emergency medical research and our clinical trial.

The interviews with families of patients are vivid, rich with detail borne of the boredom of waiting alone—due to Covid policies limiting hospital visitation to a single guest per patient—for patients to come out of surgery. Though they are robustly emotive, these interviews tell only part of a much larger story. They capture brief snippets of interactions which often lasted well beyond the interviews themselves. As my interviewees waited unaccompanied for their loved ones to come out of surgery, I sometimes eased the aloneness of the wait. On one occasion, for example, when a surgery ran several hours overtime, I cleared my schedule and sat with my interviewee for over four hours beyond the duration of the interview. We giggled over pictures of our pets. I bought her a coke because only hospital employees were allowed in the cafeteria and she hadn't brought enough to eat or drink, having not expected to be in the waiting room so long. I clenched her hands in mine when she cried as she received news of a complication and then no news at all for several more hours. The relationships I forged with the family members of patients are apparent in our interviews. They come to trust me, and in doing so, come to believe in our clinical trial—to accept the idea of relinquishing control over healthcare decisions so long as such control is placed in the hands of my clinician scientist colleagues.

For me, our community consultation interviews are a diary of sorts, documenting life over much of the pandemic. In these interviews, my interviewees and I joke about the extreme and often undignified measures COVID forced us to take. One interviewee and I chuckled tiredly as we debated whether we preferred to hang out with friends outside, risking frostbite, or inside, risking COVID—a question which was funny only in its stupid, humble quest for normalcy in a world so clearly unfit to deliver. Another interviewee and I laughed about our attempts to avoid public bathrooms before we understood much about the spread of COVID. I had been terrified that I might contract COVID from using a public bathroom, my fear of the virus instilled when I observed the crippled lungs of a patient with COVID, severed impotently and awaiting transplant in their chest which was flayed open on an operating room table. The patient died several days later. When the interviews were over, I often trudged back to my team's office, closed the door, and laid on the floor. I didn't know how to function. Sometimes I couldn't bring myself to go home because it felt so unfair that I could simply walk out the hospital doors, sink into my bed, flip open a book, and eat dinner while others were bound comatose to life-sustaining machines. Instead of going home, I'd dig into data analysis as the evening slipped into morning, falling asleep on the office floor only to wake and find I'd wept into a pile of scrubs I'd stuffed under my head.

Determining Adequate Community Consultation: Entextualized Motives

When the IRB says that the interviews I conducted are not enough, in my exhaustion I conclude that I have no idea what will be enough. Methodologically, however, I'm also unsure why the interviews are not enough. "*What could the IRB possibly be looking for?*" I plead with one of my team members. And in reframing my initial question about what was missing from our community consultation data set towards a newfound focus on the IRB as an interlocutor who

determined that something was missing from our data set, I suddenly call my own attention to the discursivity of regulatory review and pursuit of EFIC approval. The IRB's insistence that we conduct focus groups tells us more about the politics of pursuing EFIC approval—the multichannel sign configuration of which approval is both part and precipitant—than the focus groups themselves will tell us about how best to respect patients' wishes when conducting our trial. Our doubts about the potential for focus groups to yield valuable feedback relative to the IRB's belief in the contrary begs consideration of how feedback comes to be seen as valuable in the context of community consultation. Why must certain communities be included in community consultation while others need not be? Which aggregates of people constitute a "community" under what conditions for whom? A representative of a community? Are there interactional conditions for community membership? How do clinician scientists and IRBs determine who from relevant communities should be consulted? What premises must be accepted in order to conclude that interactions with these persons informs how those enrolled in EFIC trials might feel about having been enrolled? What premises must be accepted in order to conclude that feedback from these persons tells us something meaningful about how those enrolled in EFIC trials might feel about having been enrolled? Given that Blackness is widely associated with barbershops, hair salons, and churches, and locally associated with 'West Philly,' the IRB's insistence that we conduct focus groups featuring recruits from barbershops, hair salons, and churches in West Philadelphia begs critical examination of the way in which assumptions about race form foundations of community consultation methodology.

The IRB's determination that our interviews are insufficient frustrates but does not surprise us. When policymakers penned EFIC regulation, they maintained strong interest in encouraging context-sensitive approaches to community consultation and thus drafted this aspect of the

regulation in such a manner that it is open to local interpretation.[13,14] Specifically, EFIC regulation lacks directives for how to approach community consultation and FDA guidance for interpreting EFIC regulation, though endowed with some directives,[7] too leaves much regarding community consultation open to local interpretation. My interviews with clinician scientists recruited from a multitude of EFIC trials and EFIC trial sites across the US evidence this local interpretation. Interviewees used a wide range of community consultation practices and were held to a wide range of standards for adequate community consultation by their IRBs. Attesting to this range when asked how much community consultation is enough, one interviewee replied:

> I . . . think you have to reach a certain population number. I think if you say, yeah, I did . . . six to eight events, but I only have 50 people that I spoke to, then that's too little . . . I think it's hard to measure . . . I think that's actually a hard question for the IRBs to determine because every IRB has a different criteria for what is adequate for a study . . . But I want to say more than 100 people surveyed in total.

That our IRB determined our interviews were insufficient to satisfy their community consultation expectations is unsurprising in-part given the high bureaucratic stakes—precipitated by EFIC regulation's demand for local interpretation—of approving trials under EFIC. By interpreting EFIC regulation themselves, IRBs become critically implicated in the outcomes of EFIC trials, and relatedly, can become the targets of public backlash arising in response to EFIC trials for which they grant approval. That EFIC can render IRBs vulnerable was made particularly apparent in the case of Northfield Laboratories' PolyHeme Trial, a study comparing two treatments for hemorrhagic shock. This trial, approved under EFIC by multiple IRBs, provoked controversy on several fronts ranging from concerns about safety to disapproval of participant enrollment without consent.[15–17] The IRBs that approved this trial faced intense scrutiny from

both legal and lay actors.[15–17] Such scrutiny was largely levied through open letters,[15–17] and was thus highly visible to those in the regulatory world, ultimately becoming entextualized[18] as a narrative of IRB vulnerability. Widespread uptake of this narrative is evident in accounts of IRBs' experiences approving clinical protocols under EFIC. These accounts reveal IRBs' concerns about both legal culpability and negative public perceptions of institutions that grant authority for researchers to enroll participants without informed consent.[19,20] Given the perceived high bureaucratic stakes of approving EFIC trials, there is motivation for IRBs to request as much community consultation as is reasonably enforceable, as seen in my team's experience.

The ways in which IRBs measure how much community consultation EFIC clinician scientists have undertaken and set thresholds for what constitutes enough community consultation are complex. When asked explicitly how much community consultation was enough to satiate their IRBs, my clinician scientist interviewees tended to toss around specific (albeit ranging) numeric thresholds for total community consultation events and respondents. However, review of these interviewees' processes for securing IRB approval and consideration of my team's experience doing so suggest alternative criteria for approval. That is, IRBs are not simply concerned with the total number of community consultation events hosted and respondents recruited by EFIC scientific personnel, but the format of these events and the demographics of respondents.

Community Consultation Methodology

The broadest demographic categories of interest to IRBs reviewing EFIC protocols are 'disease communities' and 'geographic communities.' The EFIC clinician scientists I interviewed referenced these categories frequently, explaining that they recruited community consultation respondents whom they and / or their IRBs identified as members of disease and geographic communities. These categories also entered into my team's experience with the IRB. Our IRB

rationalized their stipulation that we conduct focus groups with recruits from barbershops, hair salons, and churches in West Philadelphia on the basis of these categories: our interviews with patients, their caretakers, and clinicians reflected only the perspectives of the disease community, not the geographic community, our IRB reasoned; however, focus groups with recruits from barbershops, hair salons, and churches in West Philadelphia, they explained, would attend to the geographic community.

Notably, the disease community and geographic community concepts employed ubiquitously by researchers and IRBs are not specifically prescribed by federal EFIC regulation. EFIC regulation states only that consultation must be carried out "with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn."[6] Though federal guidance on interpreting EFIC regulation—which IRBs tend to treat as binding—makes direct reference to disease and geographic community consultation,[7] records show that investigators used these concepts prior to development of the guidance.[21] This indicates that the impetus for ubiquitous employment of these concepts, evident both in the accounts of the EFIC clinician scientists I interviewed and my own team's experience, is not entirely of inscriptive origin.

The rationale for soliciting perspectives from disease communities appears to be relatively simple. The EFIC clinician scientists I interviewed asserted that those with some degree of personal experience with the disease-of-study could comment on EFIC trials in a way that was especially similar to that of patients to be enrolled in said trials. Of those with some degree of personal experience with the disease-of-study, my interviewees claimed that those who had fallen ill with it (e.g., survivors, current patients) were most fit to offer perspectives in line with

the perspectives of patients to be enrolled. Showing this logic in practice, one interviewee explained:

> We actually picked cardiac arrest survivors and contacted each of them to see if there was anything about the study that if they were in that position – since they have been in that position – that they would not enroll or anything that concerned them where they would be like, yeah, this would not work out.

Interest in consulting those with disease-related experience rests on two premises (discussed later in more depth): 1) that disease experience is a strong predictor of patient attitudes towards EFIC trial enrollment, and 2) that predicting patient attitudes towards EFIC trial enrollment are of ethical import. Given these ostensibly reasonable premises for consulting disease communities, we are left with the question: What does geographic community consultation offer that disease community consultation does not?

To address this question, let's consider two datapoints: 1) our IRB's concern that our interviews with patients, their families, and clinicians—all of whom we recruited from the trial site—did not shed light on the perspectives of the geographic community and the correspondent stipulation that we conduct focus groups with recruits from sites iconic of Black social life in order to mitigate this concern, and 2) the fact that the clinician scientists I interviewed frequently reported visiting sites associated with racial minorities, such as Black churches, in order to ascertain the perspectives of geographic communities. Suggesting the importance of considering race and ethnicity when consulting geographic communities, one interviewee stated:

> [Y]ou have to look carefully at the demographics of your area and make sure that the demographics of your results reflect the demographics of your area. And if there's certain

> – in our area, there's certain ethnic minorities that have larger populations here, and so even when – if their numbers aren't necessarily hugely part of the demographics of the state, they have large communities here. So, we also wanna make sure that we're reaching out to them, in particular. So, I think making sure that you are aware of what groups – different ethnic groups are in your area and could be affected. And then, making sure that your results and your efforts target that population is really important.

My ethnographic observation and interview study findings elucidate an association between race and place, suggesting that geographic community consultation presents an opportunity to solicit Black perspectives in a way that disease community consultation does not.

Interest in soliciting Black perspectives on EFIC research is unsurprising, given EFIC researchers' anxieties about minority participation in research. Detailing some of these anxieties, one of the EFIC clinician scientists I interviewed stated:

> [Researchers] are anxious. [Researchers] are afraid of lawsuits. [Researchers] are afraid of people being angry about [them] doing something. There is a mistrust of certain populations around what the biomedical research enterprise does, taking advantage of patients. There ha[ve] been a lot of research injustices in our history in this country. It's very natural I think for [researchers] to be concerned about that.

Attempt to concentrate community consultation efforts on racial minorities aligns with a broader movement to increase public engagement—and more specifically, minority public engagement—in biomedical research.[22–24] Focus groups are a popular means for soliciting supposedly 'public' voices under the banner of 'public engagement.'[25]

To fully appreciate why many contemporary researchers and research regulators find focus groups to be so alluring, it's necessary to examine the history of focus groups. Focus groups became increasingly popular in the United States in the mid-twentieth century as a means to bridge a chasm between the American elites in charge of rallying public support for World War II and the American public needed to fight the war.[26] Initially befuddled by the lack of public support for World War II, focus groups suggested to American propagandists that messaging issues were to blame: Americans, faced with visceral images of Nazis torturing civilians, were scared to go to war against the seemingly sadistic third Reich.[26] Focus groups indicated that framing the war effort using an imperialist appeal to rationality—the rational allied powers against the irrational axis powers—would be more effective at rallying American support for the war.[26] Capitalizing on the aesthetic appeal of focus groups as a means for the elite to tune in to the woes of the masses, hosting spectacle-type focus groups later became of interest to American political parties.[27] These parties became and remain so fixated on spectacle-type focus groups that journalist Liza Featherstone argues, "the focus group is a quintessential ritual of . . . 'a consumer's republic,'" saluting sociologist Erving Goffman's concept of 'ritual' and historian Lizabeth Cohen's concept of a 'consumer's republic.'[27–29] Describing the naturalness and appeal of this ritual to the American masses, Featherstone writes:

> [A] focus group is, in some ways, what democratic participation now feels like . . . It has been part of the evolution of our expressive democracy – that is, a society in which the expression of opinion has been dramatically democratised, while the distribution of everything else that matters (political power, money) has only grown more starkly unequal. The focus group offers us the experience of having a voice and the possibility of influence in a world that offers most people little control over their lives, and little

> opportunity to influence anything. “Perhaps they will use my idea!” one hopes. Maybe the movie ending I voted on will prevail, saving viewers around the world from sadness or banality. Or perhaps I’ll see my own language in this antacid commercial. A focus group – with brand managers, campaign managers and all kinds of other important people behind the mirror hanging anxiously on every laboured word of these ordinary people’s discussion – can feel like a populist triumph. It takes quite a ritual to produce that feeling.[27]

Featherstone’s explanation of focus groups’ appeal within a consumer’s republic accords with the explanations offered by some of the EFIC clinician scientists I interviewed. Suggesting that bulk of focus groups’ value derives from the discursive interaction of soliciting public perspectives, one interviewee stated:

> I think that you find that people, regardless of the type of event, if you left them with what they want to do, is they want to tell you their stories. So, they're more interested in telling you about themselves. That's probably the thing that they're most interested in doing and I think it's probably the most helpful.

Explaining why value derives from the discursive interaction of soliciting feedback rather than any changes to EFIC trial protocols made in response to such feedback, interviewees asserted that feedback obtained through community consultation rarely spurred changes. This, they suggested, is attributable to both an ethics approval timeline which situates some evaluations prior to community consultation and uncertainty about how to translate feedback into study design modifications:

> [W]ith community consultation, you're going out there and listening to [laypeople's] concerns about the study . . . Their feedback could be horrible. [laughs] It could be like, this is the worst idea ever. But it doesn't matter. We still have permission to do the study because we know that the risk-benefit is okay--that's already been approved through different grant mechanisms.
>
> [It's] really hard to know what to do with different kinds of feedback and to know what to do with different amounts of people who have enthusiasm for or are not excited about a study. . . [T]here has to be some threshold, right? . . . I think it's really hard to know what sorts of thresholds to use, and it's probably not a numeric threshold. A lot of it has to do with what people are concerned about.

Despite their uncertainty about how to deal with negative feedback, clinician scientists suggested that community consultation respondents are typically either apathetic towards or supportive of the EFIC trials proposed to them. This affect, clinician scientists suggested, hinges on the community consultation interaction. Emphasizing the criticality of the interaction between clinician scientist and respondent, one clinician scientist explained, "[O]ften it's in the sales pitch." Clinician scientists concluded that positive interactions between clinician scientists and respondents was likely to result in respondents feeling positively towards the EFIC trials proposed to them:

> So, what I've seen from a number of these sorts of situations is that the way a physician or investigative team pitches [the trial] to the public can absolutely influence their receptivity. . . It's the art of the – really, it's like a salesman. Some salesmen are very good at what they do.

Community consultation, for many of the clinician scientists I interviewed, was a public relations exercise of sorts. It is through the discursive interaction of soliciting feedback, they reasoned, that rapport with laypersons could be built, reducing friction between emergency clinical trials carried out without informed consent and public values. This rationale aligns with Featherstone's conclusion that in a nation that embraces a "culture of consultation" focus groups provide the elite with a soapbox to pass to the public, allowing talk to eclipse the public attention, which, in turn, attenuates the public's demand for (politically risky) action from the elite.[27]

Though many of my clinician scientist interviewees were adamant that rapport could be built during community consultation interactions, they did not theorize whether / how rapport built through these interactions with community consultation respondents could be commuted to rapport with those who would ultimately end up enrolled in their EFIC trials, given the statistical unlikelihood of enrolling community consultation respondents. Thus, it remains unclear how building rapport with community consultation respondents might be useful for reducing friction between clinical trials carried out under EFIC and the values of the individuals who would ultimately end up enrolled.

A few of the clinician scientists I interviewed were more explicit about the potential they saw for community consultation to reduce friction between clinical trials carried out under EFIC and the values of the individuals who would ultimately end up enrolled. Consultation with the "right" persons, they asserted, could be useful for reducing such friction. Regulators, my team's experience suggests, are even more gung-ho about this potential. Responding to a focus group facilitator guide my team submitted as an addendum to the IRB protocol for our EFIC trial, the IRB stipulated that we should open the focus group by stating the utility of community consultation. They offered several sample statements regarding this utility, including:

> [To] Inform community members about the trial in advance and provide a means for affected communities to provide meaningful input to the IRB before its decision to approve, require modifications to, or disapprove the study; [to] show respect for the community by allowing representatives of the community to identify potential community-level concerns and effects of the research; and [to] show respect for subjects' autonomy. Respect may be shown by including in community consultation activities individuals who may have, or be at risk for, the condition under study (and thereby obtain input from a group that is expected to be similar to the eventual study subjects).

These statements assume a clear predictive relationship between the values of community consultation respondents and the values of those who ultimately end up enrolled in EFIC trials. That is: the attitudes towards participation of those to be enrolled in EFIC trials can be predicted via the attitudes towards participation of community consultation respondents. Thus, if the trial is palatable to community consultation respondents, it might be assumed to be similarly palatable to those who end up enrolled.

A Semiotic Approach to Prediction

My clinician scientist interviewees who believed EFIC trials could be made palatable to enrolled participants by way of prediction thought geographic community consultation to have little predictive utility. However, the regulators with whom my interviewees and research team interact(ed) appear to understand geographic community consultation to have significantly greater predictive utility. To both understand how regulators deduce this predictive utility and assess the soundness of their deductive logics, we will leverage a semiotic approach, drawing on concepts introduced by American pragmatist Charles Sanders Peirce and extended by his

contemporaries in sociology and linguistic anthropology.

First, let's consider the ordinality of prediction. Prediction is a directionally complex meaning-making process: An agent uses individual data points ascertained through direct study of one sample to coordinate a high-level theory about that sample. The agent then calibrates the extent to which this theory applies to another sample about which the agent wishes to know but has not studied directly. To determine the transferability of the theory, the agent grades[30] the likeness between the sample on which the theory is based and the sample to which the theory might be extended. Thus, prediction, a process through which high-stakes biomedical knowledge is produced, depends heavily on the vision[31,32] and value judgements of the agents tasked with producing the knowledge (e.g., clinician scientists) and / or overseeing the knowledge production process (e.g., regulators). Semiotically-speaking, these value judgements act as ordinal catalysts, "upshifting" and "downshifting" signs between "tokens" and "types,"[33,34] precipitating parameters for scientific vision:[31,32] that is, who can be seen in what ways.

According to semiotically-inclined sociologists Stefan Timmermans and Iddo Tavory, who adeptly cut through Peirce's notoriously infelicitous language, a token is "an actual and specific thing in the world" and a type is "a general set of phenomena."[34] Drawing on ontological terminology posited by linguistic anthropologist Richard Parmentier, we can call a move from token to type "upshifting" and a move from type to token "downshifting."[33] More simply put:

> Whenever someone abstracts, generalizes, or otherwise derives a broader conclusion from a specific instance, they upshift . . . Downshifting occurs when people personalize or singularize events, actions, and emotions, leading to a respecification of both the situation and themselves.[34]

As demonstrated by Timmermans and Tavory in an article wherein they analyze racist encounters, these semiotics concepts are especially useful for appreciating discursive processes in which race figures, given that racial categories are continuously reformulated and applied to make sense of individuals by way of generalization and specification. Since my data suggests that geographic community consultation is leveraged in a racialized manner, we will now use these concepts to unpack the discursive semiotic processes through which biomedical research agents both go about leveraging geographic community consultation in a racialized manner and conclude that doing so is of ethical utility.

As is hopefully apparent at this point, the number of geographic community consultation respondents pales in comparison to the number of people that constitute the pool from which some will become eligible for EFIC trial enrollment. Thus, statistically, it is extremely unlikely that any respondents will end up enrolled in EFIC trials. (If it was possible to predict with somewhat decent accuracy who would become eligible for EFIC trials, it could be argued that persons should be consented on behalf of themselves rather than consulted on behalf of others.) Given biomedical research agents' appreciation of this unlikelihood, to impute ethical utility to the perspectives of geographic community consultation respondents, they assume that such perspectives are representative of those of the patients who will ultimately be enrolled in EFIC trials—effectually generalizing in the scientific sense of the term. Here, what are the felicitous conditions of generalization?

To address this question, it is pertinent to consider the (historical) conditions through which individuals come to be understood as representatives of collectives. Critical race theorist Karla Holloway asserts that a "readily available narrative space"—grounded in essentializations of the relationship between Black Americans and biomedical institutions—is used to make sense of

token encounters between Black Americans and biomedical institutions.[35] This narrative space explains token encounters in terms of a broader cultural dogma of Black distrust of biomedical institutions. However, it also situates token encounters in service to such dogma, rendering the dogma resistant to change. Semiotically-speaking, there is continual, bidirectional shifting between tokens and types within this narrative space. This shifting figures the minority individual (e.g., a Black person) and racial minority collective (e.g., Blacks) as fungible.[36,37]

Considering geographic community consultation, Holloway concludes that in American bioethics race has been a fundamental but shied away from condition for communitarianism.[35] So taboo is an earnest treatment of race in this sense that she terms race: the ""R" word."[38] Explaining her critique and quoting bioethicist Nancy Kass in doing so, Holloway offers:

> Bioethics arguably appreciates an implicit relationship between communitarianism and social justice, and between the ways in which "the existing formal codes and frameworks of bioethics continued to give priority to autonomy [are] a poor fit for public health practitioners seeking ethics guidance for their community-oriented work."[39] But the failure to make an explicit connection to the racialized construction of these new values, and the absence of critical inquiry regarding the ethics of a reformulated notion of autonomy when bodies that are traditionally non-white and public become the subject, is troublesome.[35]

My findings support Holloway's interpretation of geographic community consultation as a communitarian ethics endeavor to solicit minority voices.[38] But, why is such an endeavor so problematic?

To discern who from the public to recruit as geographic community consultation respondents (i.e., whose perspectives can be generalized to predict the values of the patients who will ultimately be enrolled in EFIC trials), biomedical research agents first identify patient characteristics (e.g., race, geography, ethnicity) that they believe to be predictive of patient values. Evidencing this logic in practice, one clinician scientist I interviewed remarked:

> [W]e actually look . . . at the surveys being completed and try[] to match the amount of surveys we have to the – sort of the racial makeup of our neighborhoods. So I think that we said about 65 percent of our patients at [Hospital Name] are black so we want to try to match – we want about 65 percent of our surveys that are returned to be from black patients or their families.

These characteristics are then used as stratification criteria for recruiting community consultation respondents from the lay public (e.g., investigators select for race). By virtue of these characteristics' presence in both the geographic community consultation sample and cohort of patients to be enrolled in the EFIC trial, the samples are understood to be commensurable. That is to say, these characteristics constitute gradable dimensions of likeness between the two samples, permitting the samples to be compared to one another[30] and—when deemed to be similar—for findings from the directly studied sample to be generalized to draw conclusions about the unstudied sample.

The practice of identifying value-predictive patient characteristics is one of essentialization, whereby complex, intersectional identities are segmented and reduced into categories. A person may be dissected into categories such as race, socioeconomic status, and ethnicity, for example. To perceive a category as productive, we must presume that its parameters allow it to index

something unique. Let's take race as an example. To perceive race as a productive category, we must presume that being Black is not merely symbolically different by matter of lexeme from being white, but indexically different by matter of experience. With regards to the parameters of the category 'Black,' we must maintain that if we were to extend the scope of tokens eligible for classification as 'Black,' we would correspondently need to adjust our notion of what experiences / attributes the category indexes. Framing this in terms of 'intensional' and 'extensional' definitions,[40] if modifying the extensional definition of the category does not trouble the intensional definition in any way, it must be assumed that the intensional definition is somehow failing to account for the range of attributes encompassed by the category's constituent typified tokens.

Such failures occur often, according to anthropologist Sally Merry. Commenting on categorization, anthropologist Merry warns: "[T]he process of translating the buzzing confusion of social life into neat categories that can be tabulated risks distorting the complexity of social phenomena."[41] The distortions of which Merry writes appear to be present in the case of geographic community consultation, wherein Blackness is treated as a predictor of patient values. What sort of values might Blackness be thought to predict? Why are these values of interest to biomedical research agents? And, what sorts of distortions does sampling for Blackness produce and with what social consequence?

As aforementioned, researchers often conceptualize trust relative to racial collectives, essentializing distrust to racial collectives of minority status.[42] One sociologist writes particularly keenly of this, arguing that by way of "[h]undreds of peer-reviewed papers . . . written to discern

why, under what circumstances, and with what consequences Africans-Americans express distrust . . . 'Black distrust' circulates as a biomedical truism, an empirical curiosity, and as a cultural trait unique to African Americans."[42] In my interviews with EFIC clinician scientists and in my team's experience with the IRB, this association between Blackness and (dis)trust, as well as interest in confronting distrust is evident. Speaking about strategies used to confront distrust, one of my clinician scientist interviewees explained:

> [Y]ou have to meet the population where they're at. And it'd be really helpful – and this is something that our coordinator who's a white man – or one of them. He was a white man and he knew that going into these black churches he was going to need [Laughs] somebody, essentially, who was black to talk to them. Because it's – you have – again, it's all about presentation and how you deliver something. . . [I]t won't be received well if you don't have someone who's representative of the population that you're trying to reach go with you. You know what I mean? So – yeah."

So inveterate is the essentialist association between distrust and minority collectives, 'recruitmentology' literature—what sociologist Steven Epstein terms the science of human subjects recruitment—is replete with strategies for mitigating (collective) minority distrust.[22] Epstein offers one possible explanation for this interest in trust, writing:

> The apparatus of the randomized clinical trial might properly be seen as a 'technology of trust' (to borrow a phrase of Nelly Oudshoorn's . . . and adequate trust relationships may be a central component of its proper functioning. To acknowledge this point is to

> understand why many recruitmentologists seek to go beyond the formal analysis of 'yields' and motivations to imagine the construction of new models of trust relationships.[22]

Epstein's point about yields is important to our discussion of community consultation. The percentage of community consultation respondents who are Black is often disproportionately high relative to the percentage of EFIC trial participants who are Black (CITE), suggesting, as Epstein writes of, a motivation to reimagine the lay-expert relations so critical to clinical trial success.

Yet, the intense interest in recruiting Black community consultation respondents is of questionable ethical warrant. The ability of community consultation to align emergency research with the values of Black patients is notably poor: Black patients tend to be less accepting of EFIC research than whites following enrollment in EFIC trials.[12] I can imagine two possible explanations for this phenomenon: 1) clinician scientists are unable to equitably address Black-specific concerns raised during community consultation, and / or 2) that concerns are relatively unspecific to Blackness (that is to say, 'Black' as a broad demographic category is not a strong predictor of the perspectives of patients enrolled in EFIC trials). Most likely, these factors are both somewhat responsible.

My hypothesis that clinician scientists are unable to equitably address Black-specific concerns raised during community consultation is grounded both in my interviewees' accounts of their difficulty interpreting feedback as well as my own team's struggles figuring out which types and

frequencies of feedback warrant what changes to trial design. Though my interviewees received largely neutral or positive feedback, they did sometimes receive negative feedback. This feedback often lay beyond the purview of that to which they were positioned to respond.

> [W]ithout exception, . . . people [who rejected the trial] . . . had a deep-seated mistrust, either of the medical profession in general, or the institution involved. Not a single one of them had ethical issues about the study itself. It was, "I hate blank-and-blank Hospital. My mother died there and I wouldn't let those people do research on me. I don't care what the study is."

> I had the [community consultation] booth up at Starbucks. One gentleman came up to us and I said . . . 'I just want to tell you a little bit about the study that we have going on and I can get some feedback from you.' And he's, "Well . . . all you doctors and nurses don't know what you're doing . . . I was in the ICU and they kept telling my family that I was going to die and that I was going to be brain-dead. And do I look like I'm brain-dead to you?" [laughs] … [His resistance] was totally unrelated to the research. He was just unhappy with his care.

Biomedicine has long debated the professional obligation to advocate broadly for change in social life.[43–49] Within this debate, some commentators argue that biomedicine is not structured in a way that permits professionals to intervene in social life by way of their professional roles.[46] The clinician scientists I interviewed and my team experience this acutely: the deeply entrenched healthcare disparities, of which community consultation respondents' negative experiences are token, cannot be mitigated by manipulating clinical trial design,[46] an activity which falls within the scope of our professional roles.

My hypothesis that concerns are relatively unspecific to Blackness (i.e., that Blackness as a broad demographic category is not an effective predictor of the perspectives of patients enrolled in EFIC trials) is affirmed by key findings from studies on community consultation. When residents from sites participating in an out-of-hospital EFIC trial were asked to describe their 'communities,' no respondents identified themselves as belonging to racial/ethnic 'communities.'[50] And in a study of majority-Black emergency department patients asked about EFIC community consultation, no respondents chose individuals they thought would best represent their interests based primarily on these individuals' racial/ethnic affiliations.[51] These findings suggest that race is a more complex category than it is currently treated as in community consultation. The current reductive approach fails to account for how race is a dimension of identity intrinsically entangled with other attributes and social relations[52] such as socioeconomic status, geography, gender, and education—attributes that likely confound with race to precipitate complex social, multi-dimensional experiences.[53]

In her critique of categorization, Merry raises concerns related to expertise. Specifically, she argues that the categorized constitute a cohort distinct from the categorizers and that it is the interests of the latter cohort that drive categorization.[41] Consequently, Merry asserts, "[n]ot all that should be counted is counted, nor does counting itself necessarily provide an accurate picture of a situation or its explanation."[41] Merry's concern seems to be playing out in the context of community consultation wherein the values of patients enrolled in EFIC trials are not adequately accounted for by sampling for Blackness.

To semiotically articulate a predictive relationship wherein sampling for Blackness is expected to help anticipate the values of patients to be enrolled in EFIC trials, we might say that Blackness is

supposed to index these values. That is, there is supposed to be a "correspondence in fact" between sign (Blackness) and object (values).[54] Yet, though biomedical research agents treat the relationship between Blackness and values as indexical, the inability of community consultation to align emergency research with the values of Black patients might suggest that the relationship is iconic—based on a gross caricature of sorts—rather than indexical. Mistaking an icon for an index has critical consequences here: It suggests (misleadingly) that the interests of Black patients enrolled in EFIC trials can be adequately served through community consultation.

This iconicity is a function of professional vision[31] whereby the isolation and valuation of Blackness is situated in practice.[32] While the urban hospitals at which EFIC trials tend to be sited do indeed serve substantial Black populations, the tendency to define the geographic community of an EFIC trial on the basis of Blackness means that other potentially relevant characteristics of the geographic community remain unaccounted for. That is to say, isolating and attuning interest to Blackness, and subsequently ascribing such importance to this characteristic that it is appreciated as indexical truth suggests that biomedicine's difficulty treating Black patients is in part an issue of the way in which it sees (i.e., bounds) Blackness.

Conclusion

At a focus group recruitment session, one woman remarks that she is deeply uncomfortable with the idea that her views—as a Black woman—will be interpreted as representative of the views of others. She states that she doesn't speak on behalf of anyone and refuses to participate in the focus group. Another time, I am speaking with a community partner. She draws attention to my whiteness and her Blackness, stating "Hm. So you need people who look like me—people with my skin color." In a sense, community consultation commoditizes Blackness, converting tokens into types which may be leveraged to learn things about other typified tokens.[55] Such

commoditization appears to be a prerequisite for securing EFIC trial approval. As revisions to EFIC regulation are pursued, this commoditization and the disparities it precipitates by entextualizing racialized narratives should be considered. A more comprehensive professional vision is needed.

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