

Expanding the Frame of “Voluntariness” in Informed Consent: Structural Coercion and the Power of Social and Economic Context

ABSTRACT. This paper introduces the term “structural coercion” to underscore the ways in which broader social, economic, and political contexts act upon individuals to compel them to enroll as subjects in clinical research. The paper challenges the adequacy of the concepts of “coercion” and “undue influence” in determining when research participation is voluntary. Acknowledging structural coercion shifts the frame of ethical deliberation away from specific individuals and specific studies to see important patterns in research participation by salient demographic characteristics. The effects of structural coercion manifest themselves in particular research settings, but unlike the conventional form of coercion, it is not rooted in the researcher–participant relationship or linked to particular study protocols. By extracting voluntariness from entrenched conceptions of the researcher–participant dyad, this paper proposes approaches to minimize the effects of structural coercion while creating new ethical imaginaries for review boards and researchers alike.

Whether intended or not, conceptions of informed consent are often rooted in archetypal notions of the researcher and prospective study participant. The former is assumed problematically to be a disinterested yet humanitarian individual who is well trained to conduct robust science. The latter is often characterized as being motivated by some altruistic notions about the contribution to science and society they are making even as they seek some personal benefit from the research. Cast in a dyad, the researcher has the responsibility to inform the participant thoroughly about the purpose of the research, the risks and benefits of participation, and any alternatives to research available, as well as the participant’s right to withdraw from the study at any time. The prospective study participant, in turn, has the responsibility to take

an interest in the information being communicated about the study, read the informed consent form carefully, and ask questions when in need of further clarification. The influences of larger social, cultural, economic, and/or political realities are almost extraneous within this rubric.¹ Indeed, the idealized process of informed consent seeks to minimize or eradicate the effects that social context can have on the researcher and especially the prospective study participant. In practice, however, there is now a large body of evidence that emphasizes the profound effects that social and economic contexts have both on researchers' and participants' decision-making (Bosk 1995; Chambliss 1996; De Vries 2004; Eckenwiler 2001; Evans 2002; Featherstone and Donovan 2002; Fisher 2009; Henderson et al. 2006; Konrad 2005).

How then are we to account for the broader context of consent when considering the ethics of human subjects research? According to the Belmont Report, informed consent is valid only when three critical components are present: information, comprehension, and voluntariness. Importantly, prospective research participants must have decision-making capacity for informed consent to be valid. Much empirical bioethics research has been invested in assessing the design of informed consent forms (or other consent media) as well as subjects' comprehension of information (Siminoff, Caputo, and Burant 2004; Sugarman et al. 1999).² In contrast, significantly less of the scholarly literature has struggled with the question of how to assess the extent to which research participation is truly voluntary. Within the field, there seems to be greater consensus on the ability of ethicists—or perhaps more importantly, ethics review boards—to identify and eliminate the sources of coercion and undue influence (or inducement) that propel individuals to participate when, absent those factors, they otherwise would not.³

The concern of this paper is to challenge the adequacy of the concepts of “coercion” and “undue influence” in determining when research participation is voluntary. Specifically, these terms contribute to a conservative approach to ethics that neglects the social and economic contexts of research by placing those domains outside the informed consent process. I argue instead that voluntariness must also include accounts of how “structural coercion” shapes prospective participants' decisions to enroll in biomedical research studies, particularly clinical trials. By attending to structural coercion, discussions of ethics can better capture the lived experiences of research participants.

COERCION AND UNDUE INFLUENCE:
A CONSTRAINED VIEW OF VOLUNTARINESS

The focus on coercion and undue influence as the sole threats to voluntariness in human subjects research is entrenched in the dyadic conceptualization of the researcher–participant relationship. These terms privilege a view of individual actors who are subjects or objects of overt instantiations of power. Commonly, coercion is understood as a direct form or threat of violence. The Belmont Report in its guidance on the principles of research ethics characterizes coercion this way: “Coercion occurs when an overt threat of harm is intentionally presented *by one person to another* in order to obtain compliance” (US Department of Health, Education, and Welfare 1979, emphasis added). Likewise, undue influence is framed as a specific offer by one individual to another to motivate the latter to make particular choices. Or in the language of the Belmont Report, “Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.”⁴

For the purposes of consent to research, what the concepts of coercion and undue influence share is a narrow focus on the power dynamics within the researcher–participant relationship. For example, there would be concern about coercion when researchers attempt to recruit and enroll their subordinates—such as staff or students—in studies because the subordinates might fear that they could lose their jobs or receive a poor grade if they do not enroll in the study. While the researcher might not be consciously aware of the power dynamic, the potential participants would sense that they have something to lose by not complying with the researcher’s request. In this framework, coercion is possible only when the researcher has leverage over potential participants who are consequently made vulnerable by their pre-existing relationship with the researcher. Coercion could take many forms depending on the type of research and the nature of the relationship between the researcher and potential participant, so the goal of a research ethics board would be to examine researchers’ recruitment plans to ensure that potential participants were not likely to feel coerced to enroll.

There is more ambiguity in defining undue influence in the recruitment of research participants. In part, this is because the line between acceptable influence (or “justifiable persuasion” in the language of the Belmont Report) and undue influence is difficult to draw. Within the ethical framework underlying US protections of human subjects, it is acceptable to

incentivize research participation in various ways in order to encourage people to enroll in a study. What is not acceptable, however, is to provide an incentive to enroll that is so persuasive or important to potential participants that they do so even though they would otherwise be strongly disinclined to take part in the study. Undue influence balances on the interpretation of what might induce someone to participate against his or her better judgment. Financial compensation is the most obvious example of an incentive that could be both an appropriate or undue inducement depending on the amount offered in exchange for research participation. For instance, it is commonly thought that nominal payments (e.g., \$20) could encourage someone to participate in a study absent other strong motivations to do so, but small amounts are unlikely to unduly influence someone to change their mind about participation when they do not want to enroll. At the same time, ethicists are often quite concerned about the offer of large stipends because of their potential to persuade individuals to take on risks they otherwise would refuse.⁵

Within the realm of research ethics review, it is essential to have a mechanism to determine appropriate incentives for each research study to ensure that consent will be voluntary. Review board members focus on the individual as they envision what might be coercion or undue influence for a typical participant who will be targeted for recruitment in the study. The process of making this determination necessarily atomizes the study so that coercion and inducements are evaluated only in the context of the study itself and specifically the informed consent process. Put simply, the focus of ethics review, therefore, is on what one individual can appropriately give to another in exchange for their participation in a specific study. There might be norms or “rules of thumb” that the review board follows for all studies to decide how much financial compensation or other incentives are appropriate (Largent et al. 2012; Stark 2012), but the potential impact of compensation on voluntariness must be assessed for each study on a case-by-case basis.

One should not underestimate the importance of eliminating—or at least minimizing—coercion and undue influence in the enrollment of research participants. This objective is clearly a vital step in ensuring that participants voluntarily consent to research. Nonetheless, limiting ethics review to these two components is a fairly conservative approach to research ethics. It protects research participants from the most egregious attempts to undermine voluntary consent without burdening researchers by placing serious restrictions on their eligible participant pool. It also allows the

use of incentives to help recruit participants who would otherwise have no interest in research or find participation in studies too inconvenient. Attention to power dynamics only *within* the researcher–participant relationship allows a fair amount of latitude in recruitment practices in order to support the research enterprise.

Importantly, in identifying only overt sources of coercion and undue influence, more subtle forms of power are allowed to remain invisible in the ethics review process. Because of the focus on specific individuals and studies, there is a systemic disregard for social structure and little attention to its effects on consent. As such, there are few institutionalized or procedural mechanisms to assist ethics review boards with evaluating social context even as boards are charged with protecting human subjects.⁶ There are undoubtedly multiple implications of this process for research ethics, but one deserves serious attention: the focus on individuals, as promoted in the ethical principles, obscures the patterns of research participation that map onto social address, especially for disenfranchised groups (Fisher 2007a).

With clinical research in particular, it is critical to recognize the role of social inequality in creating a pool of willing research participants. Poverty and inadequate access to health care are critical elements in propelling individuals to enroll in research when studies provide free access to health care providers, diagnostic procedures, and investigational drugs or offer a source of income (Fisher 2009; Lemmens and Miller 2003). This means that the un- or under-insured or economically disadvantaged might feel no choice except to participate in research to meet their needs. This widespread type of coercive force exerted on particular social groups, however, exists well outside the scope of the researcher–participant dyad. As a result, ethical considerations framed only in terms of the appropriateness of inducements to participate effectively erase the broader power dynamics that might infringe on the voluntariness of consent. Recently within bioethics, some scholars have even argued that some forms of exploitation are appropriate because the poor are better off participating in research than being excluded (e.g., Wertheimer 2011), but this ethical position lacks a substantive engagement with social justice. To incorporate a more robust ethical analysis of the operation of power, the existing guidance for review boards must broaden the view of coercion to include structural risks of harm.

STRUCTURAL COERCION:
A CONTEXTUAL ASSESSMENT OF VOLUNTARINESS

The importance of social, cultural, economic, and political contexts should not be underestimated in research. The individual is situated simultaneously within multiple milieus that can contribute to the desirability of participating in a study. These contextual factors will clearly influence individuals' decisions to enroll in research, but it is analytically useful to see these not as unique and personal but as structural characteristics. Illness and financial hardship (and especially the combination of the two) are two factors that could make the decision to decline participation in clinical research impossible. For research participation to be truly voluntary, people must have—and perceive to have—multiple options from which to choose. Otherwise, the “choice” to participate in research is not really a choice at all. Thus, as context limits the options that individuals have, it is necessary to identify the impact of these constraints on informed consent.

I use the term “structural coercion” to underscore the ways in which broader context acts upon individuals to compel them to enroll in research.⁷ Acknowledging structural coercion shifts the frame of ethical deliberation away from specific individuals and specific studies to see patterns in research participation by class, race, ethnicity, sex, and other demographic characteristics. Of course, the effects of structural coercion manifest themselves in particular research settings, but unlike the conventional form of coercion, it is not rooted in the relationship between the researcher and participant or linked to particular study protocols. Structural coercion occurs primarily outside of the research clinic, yet shapes the ways in which potential participants perceive the researchers and institutions, as well as how they interpret information about specific studies. The individual is subject to structural coercion, but to minimize its effects, the point of intervention is not the individual but rather the salient aspects of their social contexts, which for researchers tend to be well beyond the scope of their practice.

One might question how coercion could be structural when, by definition, it must be tied to a threat of violence. Because the model of power no longer privileges individuals, structural coercion can operate without any threat of overt violence because the violence too is structural. *In contrast to conventional forms of coercion, the threat of violence is not tied directly to the research opportunity.* Indeed, potential participants may turn to research in order to mitigate the threat of structural violence. To better understand the ways in which structural coercion impedes the vol-

untariness of consent, it is necessary to explore more fully the workings of structural violence.

Structural Violence as Context

Scholars within anthropology have written extensively about the harms to people around the world that result from structural violence (e.g., Anglin 1998; Farmer 1996, 2004; Maskovsky 2005; Rylko-Bauer and Farmer 2002; Schepher-Hughes and Bourgois 2003; Sunder Rajan 2007). Physician–anthropologist Paul Farmer and colleagues (2006) provide the following definition:

The term “structural violence” is one way of describing social arrangements that put individuals and populations in harm’s way. The arrangements are structural because they are embedded in the political and economic organization of our social world; they are violent because they cause injury to people (typically, not those responsible for perpetuating such inequalities). . . . National health insurance and other social safety nets, including those that guarantee primary education, food security, and clean water, are important because they promise rights, rather than commodities, to citizens. The lack of these social and economic rights is fundamental to the perpetuation of structural violence. (e449)

Within anthropology, the theoretical impetus to describe structural forms of violence was to draw attention to the multiple, everyday forms of oppression that shape people’s life chances even in times of peace (Schepher-Hughes and Bourgois 2003). Linked to analyses of social inequality, the concept of structural violence emphasizes the material injury that results from differential access to capital and human services, such as housing, education, and health care. By stressing the importance of human security,⁸ structural violence depoliticizes the individual as the source or recipient of harm in order to illustrate the oftentimes invisible, discriminatory forces undergirding society (Farmer 2004).⁹

Although anthropologists have largely focused on structural violence in the developing world, there are myriad examples of how it manifests in the United States. Two important settings in the US for examining structural violence have been in the welfare and health care systems. Neoliberal policies advanced by Republicans and Democrats alike since the 1980s have led to the privatization of social services, allowing corporations to profit from public programs and restricting the benefits that citizens receive from those services (Duggan 2003; Giroux 2004; Harvey 2005). With the 1996 welfare reform, for example, requirements to work in order

to receive state assistance have advantaged companies by subsidizing the cost of employee wages. At the same time, however, these policies penalize struggling families by undermining informal care structures for single parents in exchange for what usually amounts to less than a living wage without benefits and little job security (Piven 2001). Forced between the impossible choice of forgoing any public assistance or submitting to the constraints imposed by the welfare system, impoverished Americans face an entrenchment of poverty as a result of the simultaneous loss of economic opportunities brought about by de-industrialization and globalization (Schram 2006). Moreover, with increasing surveillance of the poor, those on welfare are increasingly finding that they are not integrated into but subjected to the high-tech economy (Eubanks 2011; Gilliom 2001). Morgen and Maskovsky have argued that “Welfare-state restructuring can also be conceived as one of a number of sites where the boundary between coercion and consent is being redrawn in the remaking of the neoliberal state” (2003, p. 330). These political and economic forces must be seen through the lens of structural violence in order to make visible the everyday harms that are inflicted on—as well as perpetuated by—people living in poverty (Bourgois 2003).

Health care, in contrast to welfare, has become increasingly and overtly commodified as part of neoliberal reforms (Chambré and Goldner 2008; Frank 2002; Henderson and Petersen 2002). The rise of managed care and for-profit hospital systems provides compelling examples of the corporate takeover of health that began in the 1980s (Gray 1993; Scott et al. 2000; Sloan 2006). One of the rationales for reforming health care through these institutionalized measures has been to control costs, by restricting unnecessary diagnostic tests or procedures through managed care and by increasing buying power and consolidating expenditures on supplies and equipment through for-profit hospital networks. Yet, the result has been less about cost control and more about redirecting profits away from providers and to corporations. In addition, the pharmaceutical and insurance industries have been the beneficiaries of federal health care reforms that have generated significant gains in their earnings. For example, under President George W. Bush, Medicare reform that created a prescription drug benefit has been estimated to have generated \$3.7 billion in the first two years (US House of Representatives 2008).¹⁰ Similarly, the insurance and pharmaceutical industries were largely supportive of President Barack Obama’s healthcare reform efforts that culminated in the 2010 Patient Protection and Affordable Care Act because of their ability to profit from

the anticipated expansion of their markets facilitated by this legislation (Oberlander 2010).¹¹

In spite of federal measures to try to increase access to health care, these reforms continue to underscore the profound social inequalities that structure the types of care available to people based on their social address (Horton 2006). From a structural violence perspective, lack of reliable and affordable access to health care is important for understanding the context of the persistent patterns of health disparities that lead not only to poor health status but also to poverty and joblessness. Market-based solutions to these problems are unlikely to alter the “lived experience of those who come to embody such inequalities of access” (Rylko-Bauer and Farmer 2002, p. 477).

Clinical research is inflected by the structural violence entrenched in the broader political and economic systems.¹² Because of its diffuse pattern in multiple realms, structural violence has contradictory effects on trial participation. On one hand, people with inadequate access to medical treatments through standard medical care might feel compelled to enroll in a clinical trial because they believe this will offer them the only opportunity to treat their illnesses (Fisher 2009; Kolata and Eichenwald 1999).¹³ On the other hand, however, denial of access to clinical trials can be one additional form of structural violence that disenfranchised Americans experience. For example, impoverished people in the United States often have difficulty enrolling in HIV clinical trials that would provide them with affordable or free access to expensive antiretroviral drugs (Rylko-Bauer and Farmer 2002).¹⁴ This is because researchers have concerns about those patients’ ability to adhere to complex research protocols. While adherence problems are frequently framed as individuals’ failure, the blame for poor outcomes can easily be traced to structural problems (Maskovsky 2005). In other words, structural violence can underlie both the inclusion and exclusion of patients from clinical research, depending on the kind of harms individuals face and degree to which they are subjected to social and economic inequalities. These variations in experience of structural violence provide some insights into how *structural coercion* operates within the research enterprise.

Examples of Structural Coercion in Clinical Research

Structural violence is part of the power dynamics that shape opportunities and choices in multiple domains of life. The threat or risk of harm stemming from a society rife with inequalities acts as a source of structural

coercion for individuals. For example, poor and minority women in the United States have long faced both overt and structural forms of coercion when they are asked to consent to birth control, sterilization, and abortion (Schoen 2005). Similarly, the process of consent to research is loaded with complex factors that act both as incentives and disincentives to enroll in clinical studies and that are likely to supersede the specific, detailed information about those studies.

What is often characterized by researchers and ethics scholars as participants' "desperation" can influence people's perspectives that a clinical study is their only chance for an effective therapy or needed income (Appelbaum, Lidz, and Grisso 2004; Dresser 2009; Minogue, Palmer-Fernandez, and Udell 1995). Belief that clinical trials will offer treatment to research participants is not merely a therapeutic misconception; it can also be a translation of a hope for any treatment at all. For example, there is the commonly cited type of research participant who is looking for a magic bullet because her therapeutic options for a terminal or degenerative disease have run out. In a case like this, the source of structural coercion might be only the failure of the health care system to ameliorate the particular disease,¹⁵ but it also could lie in the dependence of family members or others on that individual's economic contributions—whether formally through wages or informally through unpaid labor—to the family.

There are also the less acknowledged—but highly prevalent—research participants who have no health insurance or inadequate coverage (Fisher 2007b). These research participants are motivated to enroll in a clinical trial not only because their illness might be helped by an investigational medication but also because it allows them to interact with physicians and nurses and gain access to diagnostic tests or procedures (Pace, Miller, and Danis 2003). One telling example of this was a patient who was enrolled in a Phase I (safety) study for a drug being developed to treat Alzheimer's disease. During the informed consent process, it became clear that her son understood that the study would not help her condition or slow the onset of symptoms but that she would receive diagnostic benefits unavailable through Medicare (Fisher 2006b). Structural coercion is at work in cases like this because the health care system does not necessarily address the complex needs of patients and their families even when those patients have some form of health insurance. In this context, clinical trials appear to be the best choice because prospective participants feel as though they do not have any other options to get the care they need or desire.

A final type of research participant is also clearly subject to structural coercion. This is the participant who is unemployed or behind on bills and needs a source of cash and sees clinical trials as an avenue to earn income.¹⁶ While many clinical trials have some small financial incentives associated with them, usually to compensate participants for their time and travel, studies that recruit healthy volunteers are the ones that have the most possibility for collecting significant stipends. Phase I research facilities that specialize in studies that enroll healthy volunteers tend to pay \$200–400 per day, so depending on the length of the study, participants have the opportunity to earn thousands of dollars in exchange for taking an investigational drug and reporting its side effects (Abadie 2010). This amount of money for participants holds the promise of helping them keep their housing, feed their families, and so on. Healthy volunteers have been found to rationalize that the financial benefits outweigh the physical risks of participation by claiming trust in the research staff, physicians, and institutions at which the studies are conducted (Corrigan 2003). This could be interpreted to mean that participants put less emphasis on the specific details of studies because of their combined financial need and their broader trust in the research system.

How does the context of participants’ consent become structural coercion instead of merely an explanation of their motivations? In part, the answer to this question depends on participants’ range of viable options—including but not exclusively clinical research—from which to choose. The other critical component to the evaluation of the extent to which structural coercion could be occurring is the informed consent process itself. Within the context of structural coercion, potential research participants are not weighing the risks and benefits of a specific study (as the idealized informed consent process is conceptualized), but rather they are taking into account all the social, economic, medical, as well as any others risks and benefits that drive their interest in clinical research. The nature of participants’ engagement in the informed consent process could provide confirmation of structural coercion and, thus, important hazards for ethically valid consent. Specifically, one metric would be the degree to which participants are actively seeking information about the research study as part of their decision-making regarding enrollment. There is much evidence from empirical studies, however, that many participants, especially those who are seeking health care from studies, are not interested in the details outlined in consent forms and have few questions about the protocols (Corrigan 2003; Fisher 2009; Rabin and Tabak 2006; Zussman 1997).

More revealing evidence of the impact of structural coercion on individuals' consent to clinical trials is that there is little indication that prospective participants perceive they have choices *among* studies in which to enroll or actively compare their research options (Joseph and Dohan 2009a; Stacey et al. 2009).¹⁷ In other words, when presented with a single research opportunity, participants feel compelled to take it rather than “shop around” for potentially better studies. This means that they might not be maximizing the benefits they are seeking from study participation or minimizing the risks of harm that could result. The context of structural coercion—or the circumstances that make participants experience some degree of desperation—means that the informed consent process alone cannot be used to empower or protect participants.

PRACTICAL APPROACHES TO AND CHALLENGES ASSOCIATED WITH MINIMIZING STRUCTURAL COERCION

After acknowledging that structural coercion might constrain individuals' ability to provide voluntary consent, the question emerges of what does this mean for regulatory reform, ethics review, or recruitment of research participants. To be fair, the current regulatory focus on overt coercion and undue influence makes sense from the perspective of researchers. Specifically, is it a fair burden on researchers to be expected to account for social structure in the recruitment of study participants? And importantly, would this have negative implications for the principle of justice by excluding some people from participating in research? Justice, of course, is concerned with the distribution of the benefits and burdens of research among groups, especially enhancing access to clinical trials and minimizing threats of exploitation for specific groups. There are nonetheless a few points that can be fleshed out to think better about how the research community can manage—if not mitigate—structural coercion in action. Unfortunately, however, the primary message for researchers is that there is not much they can do to *eliminate* structural coercion because it operates outside of the dyad.

First, one practical approach to the problem of structural coercion is to intervene in the informed consent process. As discussed above, potential participants might not recognize their options within the realm of clinical research, and they might feel as though they need to enroll in the first clinical trial of which they become aware. Currently, researchers are required to provide information to prospective participants about the alternatives that they have beyond the research study. In practice, the fulfillment of

this obligation generally entails spelling out for participants the available options that exist in standard medical care. If individuals cannot access those alternative therapies due to lack of health insurance or other barriers, the framing of this information might confirm for them that they do not have any other options at all. Providing details about other research studies or sources from which prospective participants could access information about open and recruiting clinical trials could enable more selectivity with participation. If prospective participants understand that there are many potential research opportunities to consider (as patients or healthy volunteers), they might become more interested in learning about and weighing the risks and benefits of different studies. Some researchers might assert that informing participants about alternative research options is too burdensome, especially when they are concerned about enrolling sufficient numbers of participants in their own studies. While it is true that an informed consent process modified in this way might encourage participants to consider researchers’ “competition,” the goal of this recommendation is not to aid recruitment for specific studies but instead to minimize the risk that structural coercion is invalidating voluntary consent.

A second approach to managing structural coercion puts less emphasis on the informed consent process and attends more to the structural conditions underlying the threats to voluntariness. By acknowledging the importance of contextual factors in shaping individuals’ decisions to enroll in research, it allows for a frame shift away from concerns about undue influence within the researcher–participant dyad to increased attention to the possibility of exploitation. Offers of large stipends or post-trial access to experimental drugs or care are often flagged by ethics review boards as undue influence, but in the context of poverty and inadequate health care, the failure to compensate individuals appropriately for their participation could be viewed as exploitative (Elliott and Abadie 2008). An effective method to address structural coercion in research would be to confront the material reasons that motivate people to participate in research studies. On the policy level, this translates into advocating for a higher minimum wage and universal health care, both of which could significantly mitigate structural coercion.

In the clinic, however, researchers might feel frustrated by needing to attend to structural coercion. As Paul Farmer and colleagues assert, “medical professionals are not trained to make structural interventions. Physicians can rightly note that structural interventions are ‘not our job’” (Farmer et al. 2006, p. e449). Even if researchers become sensitized to

how the broader context of participants' lives influences their decisions to enroll in studies, they might feel as though there is nothing that they themselves can do about it because there are not easy guidelines for enrolling participants more ethically. That said, researchers can be attentive to these structural needs by providing participants more substantive care or health education during clinical studies, post-trial access to care (even if not to medications per se),¹⁸ and fair stipends that reflect the burden of time and effort associated with participation. Researchers can also learn how to minimize their own biases against disenfranchised groups, especially the poorest of the poor, by recognizing that these problems are not moral or individual failings but structural constraints (Metzl 2010). This framework in the clinic will not change the underlying causes of structural coercion, but it can enhance the participation of groups and minimize exploitation. Without more systematic changes in the broader political economy, however, this recommendation might simply create more inducements to participate in research, so this change can be seen more in terms of reducing the structural violence experienced by those participants than mitigating structural coercion per se.

A third approach to solving the problem of structural coercion in research is to broaden the discussion about what makes research ethical. For biomedical researchers, there seems to be a frequent conflation of ethical research and “good” informed consent. Improving the informed consent process, however, is not synonymous with improving the ethics of research. For example, one might ask: Are we doing a good job informing socially disadvantaged people about the benefits and risks of research? The answer to this question is likely affirmative. Researchers—especially study coordinators—admirably persevere at getting prospective participants of all socioeconomic backgrounds to pay attention to and read carefully information about specific studies (Cox 2002; Fisher 2006a; Mueller 2004). Nonetheless, the provision of information and the opportunity to have questions answered do not ensure that research is ethical, especially when participants are disenfranchised or otherwise vulnerable. Or put another way, informed consent does not solve the problem of structural coercion. Rather than worrying so much about the possibility of research to exert undue influence over participants, the field of bioethics must examine the ways in which the research enterprise is embedded in broader political, economic, and social contexts that pattern who is likely to view study participation as valuable. Extracting voluntariness from the entrenched conception of the researcher–participant dyad and expanding it to include

analyses of structural coercion will facilitate the creation of new ethical imaginaries for review boards and researchers alike.

CONCLUSION

Informed consent is a cornerstone of the framework for human subjects’ protections in the United States, yet even when it can be said to have technically been acquired, the process of informed consent in research often nonetheless fails to achieve its purported ends. In this paper, I have argued that ensuring voluntariness in research participation cannot be done merely by monitoring overt coercion and undue inducement. These concepts rely on a conservative view of power that is artificially constrained by the researcher–participant dyad and neglects to account for the larger social, cultural, economic, and/or political realities that intersect in ways that make research participation appear to be the only choice an individual can make. I propose the concept of “structural coercion” as a way to acknowledge how threats of harm—physical or otherwise—in individuals’ social context can induce people to participate in research. It is important for the field of bioethics to move beyond the researcher–participant dyad and more rigorously engage the context of research in order to better advance theories or guidelines for ethical research. Broader discussion or debate—as well as empirical research—about how structural coercion can be mitigated is needed to enhance research participation.

NOTES

1. I am presenting a somewhat simplistic vision of the researcher–participant dyad here in order to show how the focus of research ethics tends to rest on individuals. This is in important contrast to the expanded notion of context that I am arguing for in this paper.
2. Empirical research on the information contained in informed consent forms and participants’ comprehension of that information have had different goals and methods, yet most of these studies can be seen as having the aim of making informed consent a more powerful tool in transmitting information to individuals for their decision-making about participation in studies (Verheggen and van Wijman 1996). Although results have varied from study to study, review articles and meta-analyses have discovered very consistent findings among these studies. For example, empirical studies on informed consent find that (1) most patients have significant gaps in their recall of pertinent information about the studies; (2) physicians do not communicate information as well as they should, or they put a positive “frame” on the

- details; (3) interviews with nurses lead to subjects being better informed overall, especially about the voluntariness of their participation, the right to withdraw from the study, and about alternative treatments or therapies; (4) highly detailed information about the studies does not lead to stress or anxiety, and (5) the provision of too much information can lead to less comprehension (Edwards et al. 1998; Siminoff, Caputo, and Burant 2004; Sugarman et al. 1999; Verheggen and van Wijman 1996). A major limitation of many of the hundreds of empirical studies on informed consent is that the process of subjects' giving their consent has been examined as if it occurs in a vacuum.
3. One major exception exists in the literature on this point. As a field, bioethics has spent much intellectual energy puzzling over the question of how much financial compensation for study participation is appropriate and when a monetary benefit becomes an "undue" inducement (Ashcroft 2001; Cryder et al. 2010; Dresser 2001; Grady 2001; Kuczewski 2001; Menikoff 2001; Permuth-Wey and Borenstein 2009; Sears 2001; Siminoff 2001; Tishler and Bartholomae 2002). This point is explored in more detail below.
 4. Some scholars within bioethics have pointed out the conflation of the terms "coercion" and "undue influence" that takes place in scholarly and popular treatments of research, especially the misuse of the term "coercion" (Hawkins and Emanuel 2005). Even ethics review boards have trouble identifying which term to use (Largent et al. 2012).
 5. The issue of payment is an important one in Phase I clinical trials enrolling healthy volunteers (Abadie 2010; Almeida et al. 2007; Elliott and Abadie 2008; Tishler and Bartholomae 2003). There is considerable handwringing about the role of financial motivation in shaping those participants' decisions to enroll in studies. Yet there is also concern that lowering stipends will ensure that only the most desperate people will enroll in studies because others will not be appropriately incentivized for their socioeconomic position (Dunn and Gordon 2005). This is a particularly thorny issue in the context of an expected risk to participants and no direct health benefit where only financial compensation or altruism would influence prospective volunteers' decision to enroll in a study.
 6. The exceptions to this are with vulnerable populations, and then the process depends on examining only the specific context of vulnerability for the protection of human subjects, not the broader context. For instance, prisoners are considered a vulnerable population, so additional conditions apply to govern research on this group. On one hand, the regulation seems to account for the context because it is attentive to how an institutional setting affects prisoners' participation in research. On the other, however, the status of prisoner

trumps all other social categories, so that the category stands in for context while it simultaneously renders the actual context superfluous.

7. The term “structural coercion” has been used in other topical domains in academic scholarship, especially labor studies (Derr 1981; Hermansson 2005; Shapiro and Wendt 1992; Smith 1994). Most recently, Jeffrey Reiman (2012) mobilized the concept to describe social relations of property, specifically “the way patterns of social behavior work to constrain people’s choices beyond the limits of nature or morality. . . . The invisibility of structural coercion functions ideologically because it hides the coerciveness of private ownership of means of production. Its result is that transactions in capitalism appear free because they are free of overt violence” (pp. 23–24). While Reiman is not writing about informed consent or clinical trials, he has many analytic insights that apply well to the research context.
8. In a similar argument to the one being made here, Torin Monahan (2010) provides an important critique of contemporary analyses of human security to argue that the tendency to focus on individuals that is characteristic of this sphere ignores the structural forces that privilege some forms of security over others. In the post-9/11 US, national security has been cast as the most important area of government and cultural investment.
9. Not all scholars agree that “structural violence” is the correct analytic lens to view operations of power in contemporary society. For example, in a response to Paul Farmer’s paper in *Current Anthropology*, Loïc Wacquant (2004) writes that

structural violence may be strategically useful as a rhetorical tool, but it appears conceptually limited and limiting, even crippling. One can adopt “a deeply materialist approach” to the anthropology of suffering without resorting to a notion that threatens to stop inquiry just where it should begin, that is, with distinguishing various species of violence and different structures of domination so as to trace the changing links between violence and difference rather than merging them into one catchall category liable to generate more moral heat than analytical light. (p. 322)

Wacquant’s critique indicates the importance of parsing structural violence into more cogent categories of analysis. The development of the category of structural *coercion* is responsive to the need to differentiate how structural violence might manifest in a clinical research context.

10. Medicare Part D, the prescription drug benefit, is not technically a public program. Instead, it is a program that subsidizes the cost of prescription drug insurance that Medicare recipients can purchase from private insurance

companies. Congress could have included a provision that allowed the federal government to negotiate the price of drugs in order to control prescription costs for Medicare recipients and taxpayers. The absence of price control measures in the Medicare Modernization Act of 2003 has been attributed to the massive lobbying effort on the part of the pharmaceutical and insurance industries. One report found that “drug companies, insurance companies, HMOs, industry trade associations, and advocacy groups spent more than \$140 million on lobbying and deployed at least 952 lobbyists” (Ridgeway 2008). Not only is the overall cost of Medicare Part D cause for alarm from a policy perspective, but there is growing attention to how problems with the cost structure associated with Medicare Part D may lead to poor treatment adherence among patients because of the so-called “doughnut hole” in their coverage when they have to pay the full cost of prescription drugs (Polinski et al. 2011).

11. The pharmaceutical and insurance industries’ lobbyists were critical in ensuring that Congress jettisoned the public option from the legislation before the bill passed the Senate.
12. It is worth noting that clinical research too has benefitted from neoliberal policies implemented since the 1980s. Some of these legislative efforts have been aimed at increasing public–private partnerships and spurring innovations that tend to benefit corporations at the expense of US taxpayers (Angell 2004; Mirowski 2011).
13. Elsewhere (Fisher 2009), I have discussed the ways in which problems with US health care—especially patients’ inadequate access to care and physicians’ perception of diminished income—contribute to a robust interest in pharmaceutical clinical research among patients and providers alike. To link these trends in the clinic with the larger political economy of health care, I discuss clinical trials work through the lens of medical neoliberalism.
14. Likewise, cancer clinical trials tend to enroll only those patients who have health insurance (Joseph and Dohan 2009b; Murthy, Krumholz, and Gross 2004; Swanson and Ward 1995).
15. Here I am taking a political view of health care and research to assume that lack of knowledge about or therapies for specific illnesses is not a neutral phenomenon, but rather that it is a function of material and cultural resources that dictate some areas of intervention are more valuable than others (Epstein 1996; Hess 2004; Klawiter 2008).
16. Not all healthy volunteers participate in Phase I trials out of economic necessity, so structural coercion is not a standard characteristic of all study participants. Martin Tolich (2010) describes how some students participate

- in these studies to generate income for “extras—a motorbike, a camera, a surfboard, a holiday to Nepal” (p. 767).
17. In a current empirical project that I am conducting on Phase I participants, there is preliminary evidence that serial healthy volunteers—those that regularly enroll in clinical trials—might actually engage in some process of comparing studies, either to find the clinical trial with the largest stipend or avoid risks that they perceive as less acceptable. More research needs to be done to investigate how much of a deliberative decision-making process might be occurring.
 18. In the field of bioethics, there has been increased attention to post-trial access with scholars struggling over the question of when and which types of post-trial access are appropriate (Sofaer and Strech 2011).

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