



HHS Public Access

Author manuscript

Hastings Cent Rep. Author manuscript; available in PMC 2018 March 01.

Published in final edited form as:

Hastings Cent Rep. 2017 March ; 47(2): 21–29. doi:10.1002/hast.686.

Enrolling in Clinical Research While Incarcerated: What Influences Participants' Decisions?

Paul P. Christopher, MD,

Alpert Medical School Brown University

Lorena G. Garcia-Sampson,

Alpert Medical School Brown University

Michael D. Stein, MD,

Alpert Medical School Brown University

Jennifer E. Johnson, PhD,

Michigan State University

Jennifer Clarke, MD,

Alpert Medical School Brown University

Josiah D. Rich, MD, and

Alpert Medical School Brown University

Charles W. Lidz, PhD

University of Massachusetts Medical School

Introduction

As participants in federally funded studies, prisoners¹ in the United States are afforded special protections beyond those governing traditional human subjects research. Proposed research must focus on one of four permitted categories: i) minimal risk studies on possible causes, effects, and processes of incarceration, and of criminal behavior; ii) minimal risk studies of prisons as institutional structures or of prisoners as incarcerated persons; iii) research on conditions particularly affecting prisoners as a class; and iv) research on practices that are intended and deemed likely to improve the health or well-being of participants. Categories (iii) and (iv) require approval from the Secretary of the Department of Health and Human Services (typically executed by a designee in the Office for Human Research Protections). Moreover, the institutional review board (IRB) reviewing a study must include a prisoner or prisoner representative and a majority of members must have no association with the prison in which the proposed research is to be conducted. Finally, the reviewing IRB must ensure that a number of additional factors are met, including that the study's risks are commensurate with what would be acceptable to nonprisoners, that the advantages are not excessive given the living conditions within the prison, and that participation will not influence parole decisions (and that prisoners are informed of this).²

Corresponding Author: Paul P. Christopher, MD, Department of Psychiatry & Human Behavior, Alpert Medical School, Brown University, 345 Blackstone Boulevard, Providence, RI, 02906. paul_christopher@brown.edu.

These rules, in place since 1976, seek to prevent a return to past abusive research practices characterized by an unfair risk burden, coercive enrollment practices, and an absence of informed consent procedures. Yet, as a recent Institute of Medicine report highlighted, surprisingly little empirical attention has been paid to how prisoners arrive at decisions to participate in modern research.³ A few studies have examined whether prisoners identify research enrollment as coercive, and one study evaluated prisoners' perceptions of being exploited by research.⁴ Although much of this work is limited by small sample sizes or hypothetical study involvement, these data suggest that participants, at least those studied, view their involvement in modern research as neither coercive nor exploitative.

Even less is known about other factors that may influence prisoners' choices regarding research participation. McCarthy⁵ hypothesized that such influences include financial compensation, a belief that participation would lead to favorable treatment from prison authorities, insulation from prison violence, and attraction to the *risks* associated with a given study. When professionals (including researchers, IRB members, prison administrators, and ethicists) who oversee or conduct HIV/AIDS research in correctional settings were asked why prisoners would participate in such research, they speculated that the primary motivations were altruism, gaining new information and access to health care, compensation, and social support; the same group also suspected that coercion would be a potential influence.⁶ A few studies have examined other select motives. One found that prisoners, compared to non-incarcerated individuals, were more likely to be motivated to enroll in a hypothetical drug trial out of a desire to appear cooperative, avoid boredom, meet someone new, and help others; prisoners were significantly less likely than non-prisoners, however, to be motivated by compensation.⁷ Another study found that half of misdemeanor pretrial defendants who were enrolled in research about a drug court believed their study participation would help their court case and please the judge.⁸

Notably, all of these studies asked about potential influences on enrollment decisions using a list of factors judged, *a priori*, to likely be present or to have particular ethical salience to prisoner research. In doing so, they risked overlooking other motives that shape such decisions and which merit consideration, either because they serve as more influential to decision making or highlight previously unappreciated ethical concerns. The present study aimed to fill this gap by identifying a more comprehensive range of factors as reported by prisoners themselves. Our qualitative approach, guided by the extant empirical and theoretical literature on prisoner research, sought to understand the process that prisoners used to arrive at their decision to participate in clinical research. We sought to identify all factors that came to mind for participants, including both those which might have dissuaded them from enrolling and those which supported enrollment but were not necessarily the driving force behind their decision.

Methods

Participant Recruitment

Participants were recruited from six clinical research studies (hereafter, "parent studies") being conducted within a single state Department of Correction (DOC), all of which enrolled participants during incarceration (either jail or prison). Of the parent studies, three

were clinical trials testing treatments for substance dependence, one was a clinical trial testing an intervention for reducing HIV risk behaviors, one was a clinical trial testing group psychotherapy for depression, and one was a non-trial study on the relationship between substance use and incarceration. From June 2013 to January 2014, research staff from the parent studies informed current and prospective study participants (English-speaking only) of the opportunity to learn about an ancillary study on how prisoners make decisions regarding enrollment in clinical research. Those who expressed interest were later contacted by an investigator of this study [omitted for peer review] and engaged in a separate informed consent discussion; this investigator had no role in any of the parent studies. Among those who entered an informed consent discussion, only one chose not to participate. All participants provided verbal and written informed consent and were compensated for their participation in accordance with DOC policy. The institutional review board of [omitted for peer review] approved this study.

Interviews

Semi-structured interviews were conducted using an interview guide developed for this study. Interviews began with open-ended prompts (e.g., “Tell me how you came to hear about this study”) designed to encourage participants to recount how they first learned of the parent study and recreate their frame of mind when first considering whether to enroll. Subsequent questions prompted each participant to “think aloud” about any factors that came to mind when considering participation and were designed to capture individual perspectives and generate deeper reflection. As interviews progressed, questions became more specific, and participants were prompted to consider specific factors (e.g., personal benefit, pressure from others). Participants also provided demographic information: age, gender, race/ethnicity, and the highest level of education.

Data Analysis

Interviews were recorded, professionally transcribed, and proofed for accuracy. Two authors [omitted for peer review] reviewed transcriptions to identify factors related to enrollment decision making. Responses were not identified as a factor unless the participant indicated that a particular factor was considered in one’s own decision (even if not the deciding factor), as opposed to being important in general or potentially important to others. After a preliminary analysis of all transcriptions, a coding scheme was developed based on identified factors and was revised through discussion until a consensus was reached. After the coding scheme and dictionary were established, [omitted for peer review] then coded all transcripts using NVivo 10. Open coding of the first 15 transcripts was conducted to ensure familiarity with, and consistency in, the coding procedures and the intended content of the preliminary code list. The remaining 40 transcripts were coded independently. For an identified factor to be included in the final results, both coders had to agree on its presence. At the completion of the coding process, a code frequency list was generated indicating the frequency of codes in each transcript.

Content saturation, defined as the point in the qualitative data collection and analysis process when further collection and analysis cease to generate any new factors, was tested using a 3-step process: 1) the 55 transcripts were ordered chronologically and organized into nine

groups of 6 or 7 transcripts each; 2) factors appearing in the first group were identified using a saturation grid. The transcript group in which each factor first appeared was indicated by an “X”; 3) each subsequent transcript group was compared to the previous group to identify the appearance of new factors. We considered saturation reached when no new factor(s) appeared in a transcript group.

Coding quality was evaluated by determining inter-rater agreement (IRA) in the (1) identification of each instance of factors across all transcripts and (2) assignment of factors within each transcript. Cohen’s Kappa (or a similar statistic) was not used because such calculations require a predefined and finite number of items to be rated; in the present study, there were an infinite number of quotes that could be identified as factors and an infinite number of factors that could be created and applied to any given quote. Thus, to determine IRA, ten transcripts (25% of those that were independently coded) were selected (1–2 chosen randomly from each content saturation group), pairs of coded transcripts were compared to identify differences in the assigned factors, and IRA statistics were reported as the percentage of agreement.

Results

Participant Characteristics

For the 55 participants, the mean age 40.5 years (SD=8.9) and 39 (54.2%) were male. Thirty-two participants (44.4%) identified as non-Latino White, 24 (33.3%) as non-Latino Black, 13 (18.1%) as Latino, and 3 (4.2%) as a member of another racial/ethnic group. Eighteen (25%) reported their highest education as less than high school graduate or GED, 28 (38.9%) as high school graduate or GED, 15 (28.1%) as some schooling beyond high school, and 11 (15.3%) declined to report their educational level.

Content Saturation

Twenty-four unique factors were identified. Eighteen (75%) first appeared in transcript group 1, two additional factors (8.3%) appeared in group 2, and one more factor (4.2%) appeared in each of groups 3, 4, 5, and 7. These results show that nearly all factors appeared in the earliest interviews, with no new factors identified in the last two groups (8 and 9). Thus, saturation of factors that potentially influenced participant decisions to enroll was achieved using these 55 transcripts; any continuation of data collection beyond this number of interviews would have been unlikely to provide new information.

Inter-rater Agreement

IRA was between 93.2% and 100% for identification of all instances of factors across all transcripts, and between 62.5% and 100% for assignment of factors (i.e., each mention of a factor) within individual transcripts.

Decision-making

The 24 factors relevant to participant decisions are described below. Examples of participants’ responses coded for each factor are also included. All participants endorsed multiple factors. Factors were grouped into two broad categories: (1) those favoring

enrollment, and (2) those discouraging against enrollment. Within each category, factors were further grouped into (a) internal motives (i.e., relating to participants' own illness or life) and (b) external motives (i.e., pertaining to being incarcerated or being influenced by others).

Factors Favoring Participation – Internal

The factors favoring enrollment included various types of personal benefit that one expected and perceived advantages. Although several of the factors could be subsumed under a general “benefit” category, they are listed separately below to provide a detailed understanding of the different identified motives.

- a. *Desire for treatment:* Thirty-six participants (65.5%) identified a desire for treatment as a motivating factor for study enrollment, describing the study as a way to get help for existing health conditions.

Example: “*As I said because I—like, as of right now I’m still going through like certain things and I probably need help, like, to try to, I’ll say, manage my anxiety because I have anxiety, not severe, but minor anxiety. So I probably needed more help on it.*”

- b. *Compensation:* Thirty-three participants (60%) identified compensation (either money or gift cards) as a motivating factor for enrolling. Some described the money as useful for purchasing items from the commissary while others saw it as a means of financial support upon release. Although not asked directly, nine participants (16.4%) volunteered that money was not the primary factor in their decision.

Example: “*[The researchers] give you like maybe \$20 or \$30 worth of [gift] cards every couple of months or something like that for being part of the research program. ...and then those things like that can help with shampoo, soap, you know, maybe a pair of sneakers or food or something, you know, because, like me, I don’t have anything.*”

- c. *Altruism:* Twenty-seven participants (49.1%) reported being motivated by the possibility that their participation would help others with similar conditions or assist the researchers.

Example: “*I think in the future maybe it’ll help. Anything that can help the women in the prison I’m for because I know what it’s like. I’ve been coming in and out of here with my drug addiction and stuff so I want to give back as much as I can.*”

- d. *Avoid unwanted outcome:* Twenty-seven participants (49%) described a desire to avoid an unwanted outcome either during or after their incarceration. Examples included beliefs that participation might help prevent a drug relapse, symptoms of withdrawal, criminal recidivism, or worsening of other health conditions.

Example: “*I was basically sober when I went into prison and all addicts want to use again. They want to reward themselves when they get out.*”

So I thought let me take a precaution and cut that off of the path before I even put myself in that position.”

- e. *Try something new:* For twenty-six participants (47.3%) enrolling in the study provided an opportunity to try something new, either out of curiosity, interest in learning about a new subject, or having had little success with previous types of interventions. Eight of these participants remarked that participation would provide an opportunity to try a novel drug/therapy.

Example: *“I might have tried the study because I was looking for new things, see what I need for me, because I figured a way to study is they’re looking for new avenues and stuff, ways to treat people.”*

- f. *Other incentives:* Eighteen (32.7%) participants spoke about being motivated by the fact that participation offered other specific incentives, such as taxi vouchers for follow-up visits, bus passes, and temporary coverage for treatment in the community.

Example: *“Because [the research team] seems like it’s resourceful. Like, basically [the team] was going to help me, like, get into any substance abuse classes, help me with transportation if I needed it. So it seems like it would be good for me when I would get out, too.”*

- g. *Positive past research experience:* Seventeen participants (30.9%) cited being motivated to enroll because they had a positive past experience as a participant in research either while incarcerated or in the community.

Example: *“Every time I’ve been in research, it’s always been a good experience. I’ve never had a bad—and it’s always been with [name of research institution]—so I’ve never had a bad experience with them at all.”*

- h. *Improve one’s life:* Sixteen individuals (29%) viewed participation as an opportunity to gain skills, information, or support that would allow them to improve their lives. In these cases, participants identified enrollment not merely as a way to obtain treatment for an illness but also as a means to pursue personal goals, such as achieving financial stability, developing healthier relationships, and finding stable employment.

Example: *“I have lost a lot of my life from using drugs and drinking and everything like that. I want to, I would like to change, you know, and become who I should, you know, who I can be.”*

- i. *Entertainment:* Sixteen participants (29%) described having little else to do with their time and wanting to participate in something that would allow them a break from their routine, or provide an opportunity to get out of their cell.

Example: *“Because I just sit around here and do nothing all day anyway. So I feel there is something to make you busy, too.”*

- j.** *Support after release:* Fourteen (25.5%) participants described being interested in study participation because they believed it would provide social support or encouragement following release into the community.

Example: *“It’s a six months study from when I get released, which is kind of cool. They keep up with you, like, when I get released they automatically...call my cell phone to check on me and ask certain questions, like, ‘so, are you going to get treatment for your alcohol abuse?’”*

- k.** *Desperation:* Thirteen participants (23.6%) described feeling desperate, very scared, or extremely worried about the potential consequences of their illnesses, if untreated, and saw study participation as a way to mitigate this risk. Three participants (5.5%) identified death as a possibility.

Example (also coded at *Avoid unwanted outcome*): *“I was scared to get out and go back to doing drugs and overdose because I had a really bad overdose. They kept me in the hospital, it was like, I was in intensive care for three days or like four days and they said I was lucky I wasn’t brain dead.”*

- l.** *Advocacy for prison reform:* Six participants (10.9%) specifically described how their participation in the study would allow them to advocate personally for more resources for inmates by potentially influencing correctional policies. This category was coded separately from altruism, which was defined as a desire to help researchers or individuals with similar illnesses.

Example: *“Why not help with the study if it’s going to benefit us with maybe getting better classes in here or they know more of what we need?”*

Factors Favoring Participation – External

No participant described a perception of being directly coerced (i.e., threatened with harm) into joining or staying in the research study. In fact, most participants (n=43, 78.2%) specifically indicated an absence of coercive influences.

Example 1: *“The study was very strict on not forcing you...It was all up to you to do the study or not. They didn’t pressure you at all. It was either you wanted to do it, you could stop at any time (sic).”*

Example 2: *“[The researcher] said if I wanted to do it then I could, but I wasn’t being forced to do it, and it didn’t affect me in any kind of way.”*

- a.** *Constrained options:* Forty-six participants (83.6%) described being motivated to enroll because they perceived having few alternative options available to them while incarcerated, or dissatisfaction with the treatments offered by the prison. All but one of the participants from the three substance abuse trials endorsed this motive.

Example: “...I mean there’s nothing in [prison] for me. You know, there was no options for me to take, because I was doing a small sentence, so I wasn’t eligible for anything.”

- b.** *Encouragement:* Thirty-five participants (63.6%) described receiving encouragement from family members, other inmates, or prison staff to consider enrollment. None of them described this encouragement as pressure to enroll against their will or as an influence that overrode their decision-making.

Example: “My mother, she wrote me one letter while I was in here, and she was, like, why don’t you do the—I was already planning on doing it—but she was like why don’t you do that [research study]. And you know, it is where I am going from.”

- c.** *Humane treatment:* Twenty-eight participants (50.9%) perceived research staff as more likely to treat participants humanely, either by being better listeners, not judging them, or providing better care than prison treatment providers.

Example: “...I felt like [the researchers] treated me like a person and I’m an inmate, so, you know what I’m saying? It was—it’s actually kind of nice to, you know, just talk to a person.”

Factors Against Participation – Internal

- a.** *Discomfort sharing private information:* Thirteen participants (23.6%) described feeling uncomfortable with the personal nature of information they would be asked to disclose while in the study. Examples included substance use, mental health problems, trauma history, sexual activities, and criminal and other high-risk behaviors.

Example: “Like, at first I said, yeah, but then in the beginning they’re asking, like, a whole bunch of, like, personal stuff and I got, like, weird at first. So then I was like thinking I was going to quit and stuff.”

- b.** *Doubts about study being worthwhile:* Seven participants (12.7%) expressed hesitation about enrolling because they had doubts about whether the study would be worthwhile or of benefit to them.

Example: “I just wonder if this is going to be a whole waste of time.”

- c.** *Distrust in research/researchers:* Four participants (7.3%) described distrust of research in general, the researchers specifically, or the safety of the research intervention (i.e., beyond any inherent risks associated with a given protocol).

Example: “I mean the suspicion will be, am I a guinea pig? Am I one of the first people to take [study drug]? So if I am going to be one of the first people to take it, [then] I might be one of the first people to see the side effects that they don’t know about. You know what I’m saying? Like I am not telling you—I didn’t go crazy with it. I’m not conspiracy with it. But there are times when I thought, why this drug—why aren’t

the doctors using it? Why don't you hear about this in meetings? Why isn't it flashed all over?"

- d.** *Fears of getting help/better:* One participant (1.8%) in a substance abuse trial was hesitant to participate because he worried that abstinence would reveal something about himself that he was not prepared to confront.

Example: *"...And then these things might come out, that something about me and my life that I don't like about myself maybe I will learn—something about my life that scares me. I don't know, you know, it has been such a long time that I have been using drugs and all that."*

Factors Against Participation – External

- a.** *Dissuasion from peer or loved one:* Seventeen participants (30.9%) reported having been discouraged from participating by a family member, friend, loved one, or another prisoner. When the influence came from another prisoner, it tended to be a negative statement about the study or researchers (e.g., that it wouldn't be helpful, that it wasn't worth the time required, or that researchers cannot be trusted) or ascribing negative labels to participants.

Example: *"Like when [the researchers] first started meeting with people [other inmates] were like, 'oh, why are you meeting with people for psychological research? What's wrong with you?' ...Like busting chops type of thing. Like, 'oh, you're going to meet with them? Yeah, you're a nutcase.' That type of stuff."*

- b.** *Dissuasion from correctional officers:* Sixteen participants (29.1%) described being disinclined to enroll, either because correctional officers directly discouraged them from enrolling or because they had overheard officers making negative comments about the study. Eleven of these participants came from substance abuse trials.

Example: *"And [the correctional officers] actually try to get you in trouble like they did with me and get you kicked off this [study name]. They give you, they start giving you dirty urines, they book for anything, just put you in seg...so the [study name] is not in the jail... [Officer's name] said that, you know, 'I can't believe we get this F-ing study in my building' and 'if it was up to me I would just have them all shit on themselves in [segregation].'"*

- c.** *Publicized nature of participation:* Sixteen participants (29%) described how study participation while incarcerated might breach their privacy. Examples of this included having one's name called over the loudspeaker, being pressured by other inmates for information, or having correctional staff discuss one's involvement with other staff members or inmates.

Example ("C.O." is short for "correctional officer"): *"The C.O.s, they tell all your business in here. Like, if you have me in with somebody they tell another C.O. and then that C.O. when there's a point. There's a*

chance that the C.O. was friendly with another inmate. There's nothing kept private here."

- d. *Inconveniences of study procedures:* Twelve participants (21.8%) described how particular aspects of the study protocol (e.g., frequency of follow-up assessments, study duration) made them hesitant about participating.

Example: *"[Being in the study is] kind of going to be hard. You have to, like, keep in touch up to eight months after [release] which is a little long, I think. And you have to meet at, like, Dunkin' Donuts, she was saying. And you don't get the gift cards—it's spread [out over] eight months, I guess."*

- e. *Dissuasion from correctional medical staff:* Six participants (10.9%) expressed concern that certain correctional medical staff would treat them less favorably than other inmates if they enrolled because of a perception that these staff members were biased against the research study.

Example: *"[The nurses will] tell you straight up they don't like [the study]. They don't like having to deal with it. This [is] actually work for them, they don't think—they don't think they should give [the study medication] to anybody in jail at all."*

Discussion

This study is the first to investigate a comprehensive range of factors that influence prisoners' decision to enroll in clinical research. Participants from these six clinical studies described a diverse range of motives, both favoring and opposing their eventual decision to join. Many are well-recognized considerations among non-incarcerated clinical research participants, including a desire for various forms of personal benefit, altruism, and concern about study risks and inconveniences. As this study shows, however, a number of influences seem unique to prisoners and result directly from the experience of being confined in a correctional environment.

Perceived Lack of Alternative Treatment Options

Among the most commonly cited factors, for example, were the desire for treatment, the perception that in prison one has few, if any, options for certain kinds of mental health and substance abuse care other than to participate in a study, and the belief that research staff would provide more humane treatment than that delivered by correctional workers. For a few participants, enrollment was motivated by an intense fear of what might happen as a result of their illness if they did not receive help from the study. While non-incarcerated individuals may be motivated to enroll in a study because of a perceived lack of treatment options, it is typically because their illness has proven refractory to existing interventions.⁹ Conversely, for prisoners, the presumed constraint in treatment results from incarceration itself. In other words, they believe good alternatives are available in the community, just not while incarcerated. A belief that the quality of care provided in a clinical research study may exceed that of otherwise available treatment, on the other hand, is not necessarily unique to

incarcerated participants. Participants in a variety of clinical trials may at times receive more attentive care. Nevertheless, the point raised by these prisoners seems to be that the care and attention afforded to them while incarcerated is perceived as inadequate to their needs and, for some, devaluing of their dignity.

This is a troubling finding. Inmates are afforded a constitutional right to access adequate healthcare because, while incarcerated, they are not at liberty to seek their own treatment.¹⁰ Yet, a majority of the prisoners interviewed expressed a willingness to accept the risks a study poses in order to have even the *possibility* of accessing clinical care (recalling that trial participants (1) may be randomized to the non-experimental arm, and (2) that the experimental treatment may prove no more effective than the already available treatment). Thus, the views expressed by these prisoners suggest that in spite of their constitutional right, they identify both the access and quality of correctional healthcare as inadequate, at least with regard to their substance abuse and mental health needs. National data seem to validate these views, and the overcrowding of jail and prisons in the United States and the high cost of providing healthcare in correctional settings suggest that prisoners may well be competing for access to whatever treatment is available.¹¹ These findings, then, underscore a broad moral imperative facing our society: prisoners need better and more healthcare than they are currently receiving.

Such a lack of treatment options also has implications for the ethics of prison-based research. If the available care is indeed so poor, some prisoners may feel that in order to receive care they have no other choice but to participate in research. While it may be tempting to equate this sort of dilemma (i.e., choosing between entering a study and foregoing adequate care) as a kind of coercion,¹² we believe that in *the context of research* it is more accurate and constructive to frame the ethical issues in terms of the potential for exploitation and ensuring studies have an appropriate risk-benefit ratio. Recall that coercion is generally conceptualized as being present when someone threatens to harm another in order to compel his agreement.¹³ Here, though prisoners may feel immense internal pressure to enroll in order to improve their circumstances, no one is (necessarily) threatening to make prisoners worse off if they choose not to participate. A very real concern, however, is that prisoners may be unfairly exploited by research. This potential exists because prisoners are at a disadvantaged position from which to negotiate for alternative treatment options; indeed, they essentially have no negotiating power. They can only choose between continuing the status quo and accepting a study's risks and inconveniences in order to gain the possibility of getting better care. It must be conceded that insofar as research takes advantage of prisoners' circumstances to answer a scientific question, it is exploitative; the same is true for all clinical research. The more relevant question is whether clinical research under these circumstances *unfairly exploits* prisoners and, if so, whether such studies should be prohibited. The answers to these questions depend on a careful assessment of what potential benefits a study offers and the risks and inconveniences a study poses. After all, to deny prisoners the ability to access to research that may be immediately beneficial to participants and may lead to better healthcare for prisoners more generally, on the basis that it exploits their limited access to healthcare serves to thwart the very improvements in care they desire and deserve. At the same time, studies that promise little in the way of actually helping

prisoners and those that pose excessive or unnecessary risks to participants, are unfairly exploitative; prisoners gain little while researchers (and society) benefit at their expense.

Current federal guidelines for correctional-based research (as outlined in the introduction) address this dilemma by largely limiting research to minimal risk studies that essentially require prisoners or their conditions as the objects of study; unlike non-incarcerated participants, who are afforded the autonomy to independently weigh what risks they are willing to assume, prisoners require additional protections, in part, because they may be willingly expose themselves to risks that non-incarcerated individuals would be less likely to accept. Under the principle of respect for persons, then, their autonomy is restricted in the interest of protecting them from unreasonable harm, even if that means limiting their access to potentially beneficial research. A recent Institute of Medicine group, however, which reviewed the existing regulations governing prison research, recommended moving away from a category-based model for research review (i.e., minimal versus above-minimal risk) to a risk-benefit model.¹⁴ Their recommendation, grounded in the principle of distributive justice, is based on a recognition that in prisoners deserve to have equal access to the potential benefits of some types of modern clinical research, so long as those benefits are not outweighed by the risk burden. In support of this notion, emerging data suggest that prisoners desire greater access to clinical research opportunities and do not generally identify their involvement in such studies as exploitative.¹⁵

Non-Treatment Incentives for Participation

A majority of participants also cited monetary compensation (60%) or other incentives (32.7%) as a motive for enrollment. Providing compensation to non-incarcerated research participants for their time and effort is common practice, even though monetary incentives (as with all inducements) hold the potential to powerfully influence enrollment decisions. This potential may be intensified among prisoners who often face financial hardship and have limited access to remuneration through employment. Due to their limited financial resources and the severe constraints on prisoners' autonomy, some have also identified research payments to prisoners as potentially coercive.¹⁶ As others have argued (and echoing our earlier discussion of coercion) characterizing compensation to research participants (whether incarcerated or not) as coercive is misguided, since by declining to participate, one is not at risk of being made worse off than before.¹⁷ Indeed, it could also be argued that to prohibit giving incentives to prisoners, particularly when such offers would otherwise be provided to non-incarcerated participants for similar studies, unfairly exploits prisoners' circumstances. These conflicting views are reflected in the wide variability in U.S. state policies for compensating prisoner participants, with roughly half of states prohibiting payment altogether and the remainder either allowing payment or having no formal policy on inmate compensation.¹⁸ The real concern here is that incentives have the potential to override careful consideration of all that being involved in a study entails. In other words, incentives risk unduly influencing one's rational decision-making. Current federal regulations recognize this concern and charge IRBs with ensuring that the advantages to a prisoner participant "are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired."¹⁹ Yet determining what inducement (monetary or otherwise) is

sufficient to exert such a disruptive force is no easy task. For some, a very large payment may do little to distort the ability to make a sound decision; for others, even a relatively small amount may be enough to distract from considering important study aspects. Thus, in the present study, the fact that most of the prisoners were (at least in part) motivated by monetary or other incentives does not alone answer the question of whether they were unduly influenced. Nevertheless, it does point to an area for future research, namely the need to carefully examine whether prisoners' decisional capacity to consent to research is diminished by inducements.

Pressures Against Enrollment

A common ethical concern regarding research with prisoners is that prisoners will be forced to enroll. As noted, no participant in our sample reported a perception of being coerced into a study; on the contrary, most described how they were specifically (and in some cases, repeatedly) informed of their freedom to decline enrollment with assurance that it would not adversely affect their jail or prison stay. Many participants indicated that various people (ranging from family, to other prisoners, to correctional staff) encouraged them to enroll. None of the prisoners, however, described this as inappropriate pressure (i.e., overtly or covertly threatening); in fact, most volunteered that the message was perceived as an expression of support. To our surprise, however, a significant minority of participants described factors that pressured against participation. These included perceptions that participation would be publicized, that their responses to some questions would not be kept confidential, and that they might be mistreated or discriminated against by correctional staff (particularly correctional officers and, less frequently, nurses who work in correctional settings). Thus, to the extent that inappropriate pressure was placed on one's decision, the influence served to dissuade prisoners (albeit unsuccessfully) from enrolling and staying in the study over time. This phenomenon may result from the divergent goals of clinical research and incarceration. Clinical research seeks to identify effective treatments to improve prisoners' health and wellbeing; this aim may be seen as different from, if not contrary or competing with, the traditional intent of incarceration, which is to punish and remediate. Thus, it is not surprising that select correctional staff would view research unfavorably especially if it seems to provide special treatment to prisoner participants, or creates additional administrative burdens. Nevertheless, given the degree to which prisoners identify the available correctional healthcare as inadequate and seek to access treatment through enrollment in clinical research, any form of dissuasion from prison staff or prison culture is problematic.

Although each of the dissuading factors was only reported by a minority of participants, this novel finding merits further study. Specifically, one would want to know whether those who elected not to enroll or dropped out before the study ended, did so because of such types of dissuasion. To date, efforts to measure research voluntary consent among prisoners have focused on factors that direct prisoners to engage in research against their will. This is not surprising given the historical research abuses involving prisoners. Nevertheless, this study suggests that future efforts to evaluate voluntary consent should also focus on the presence of factors that seem to preclude prisoners from study participation.

Study Limitations

These findings are limited by the inclusion of studies conducted within a single state correctional department. The policies and culture of other state or federal correctional systems may produce different influences from those identified here. Similarly, we only interviewed participants from six clinical studies. Although these six represent the types of federally funded studies being conducted nationally, future research would benefit from including a broader range of studies. We included persons who were in jail (pre-sentencing) and in prison (sentenced); a larger study might examine group differences according to where persons are along the sentencing process or by expected time to release. As mentioned above, we did not interview those who declined to enroll in one of the parent studies; prioritization of the reasons for disinclination or identification of additional factors that might have influenced the decision not to enroll are not available here. Finally, as interviews progressed, and we developed a more nuanced understanding of participant decision-making, there were instances where we would have liked to return to an earlier interview to follow up on a particular topic. Despite this shortcoming, we believe the open-ended nature of our interview approach yielded information that may not have been provided if potential influences had been restricted to a pre-determined set of factors assumed to be most relevant.

Conclusion

Given the constraints of incarceration and the potential for abuse, it is important to understand the complexity of the reasons why prisoners decide to enroll in clinical research studies and identify the factors that might prevent or dissuade them from doing so. This study provides unique insight into the thought process of prisoners when making the decision to participate in clinical research. Our study findings show that the decision to enroll in clinical research is guided by a variety of internal and external factors. Some of these influences seem unique to prisoners and result directly from the experience of being confined in a correctional environment. An absence of perceived coercion suggests informed consent for these participants is adequate, while the presence of dissuasion from enrolling raises a novel concern about a potential threat to the voluntary nature of enrollment decisions.

Acknowledgments

Source of support: Funding for this work was supported by award K23DA034030 (Christopher).

Notes/References

1. For the purposes of this paper “prisoners” is used to denote both jail detainees and individuals sentenced to a period of incarceration.
2. Code of Federal Regulations. Subpart C (45 CFR §46.301–306). at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>
3. Institute of Medicine, Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research. Ethical Considerations for Research Involving Prisoners. In: Gostin, LO., et al., editors. The National Academies Collection: Reports funded by National Institutes of Health. Washington, D.C.: National Academies Press; 2006.

4. Christopher P, et al. Exploitation of Prisoners in Clinical Research: Perceptions of Study Participants. *IRB: Ethics & Human Research*. 2016; 38(1):7–12. [PubMed: 26964404] Dugosh K, et al. Measuring Coercion to Participate in Research within a Doubly Vulnerable Population: Initial Development of the Coercion Assessment Scale. *Journal of Empirical Research on Human Research Ethics*. 2010; 5:93–102. [PubMed: 20235867] Edens J, et al. Voluntary Consent in Correctional Settings: Do Offenders Feel Coerced to Participate in Research? *Behavioral Sciences & the Law*. 2011; 29:771–95. [PubMed: 22086664] Moser D, et al. Coercion and Informed Consent in Research Involving Prisoners. *Comprehensive Psychiatry*. 2004; 45(1):1–9. [PubMed: 14671730]
5. McCarthy C. Experimentation on Prisoners: the Inadequacy of Voluntary Consent. *New England Journal on Criminal & Civil Confinement*. 1989; 15:55–57.
6. Hanson B, et al. Key Stakeholders' Perceptions of Motivators for Research Participation among Individuals who are Incarcerated. *Journal of Empirical Research on Human Research Ethics*. 2015; 10:360–7. [PubMed: 26283681]
7. See, again, D. Moser et al., “Coercion and Informed Consent.”
8. See, again, K. Dugosh et al., “Measuring Coercion.”
9. Nurgat Z, et al. Patient Motivations Surrounding Participation in Phase I and Phase II Clinical Trials of Cancer Chemotherapy. *British Journal of Cancer*. 2005; 90:1001–5.
10. *Estelle v. Gamble*, 429 U.S. 97 (1976).
11. Wilper A, et al. The Health and Health Care of US Prisoners: Results of a Nationwide Survey. *American Journal of Public Health*. 2009; 99:666–72. [PubMed: 19150898] Bureau of Prisons. Growing Inmate Crowding Negatively Affects Inmates, Staff, and Infrastructure. GAO; 2012. The Bureau of Prisons (BOP): Operations and Budget Available at: <http://www.gao.gov/assets/650/648123.pdf> The Pew Charitable Trusts. State Prison Health Care Spending: An Examination. Jul 08. 2014 Available at: <http://www.pewtrusts.org/~media/assets/2014/07/stateprisonhealthcarespendingreport.pdf>
12. See Obasogie O, Reiter K. Human Subjects Research with Prisoners: Putting the Ethical Question in Context. *Bioethics*. 2011; 25:55–6. [PubMed: 21158873]
13. Anderson, S. Zalta, Edward N., editor. Coercion. *The Stanford Encyclopedia of Philosophy* (Summer 2015 Edition). Available at: <http://plato.stanford.edu/archives/sum2015/entries/coercion/>
14. See, again, Institute of Medicine. Ethical Considerations for Research Involving Prisoners.
15. See, again, P. Christopher et al., “Exploitation of Prisoners.”
16. See, again, B. Hanson et al., “Key Stakeholders' Perceptions.”
17. Smoyer A, Blankenship K, Belt B. Compensation for Incarcerated Research Participants: Diverse State Policies Suggest a New Research Agenda. *American Journal of Public Health*. 2009; 99:1746–52. [PubMed: 19696389]
18. See Wertheimer A, Miller F. Payment for Research Participation: A Coercive Offer? *Journal of Medical Ethics*. 2008; 34:389–92. [PubMed: 18448723]
19. See, again, 45 CFR §46.305(a)(2).