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Knowledge of Federal Regulations for Mental Health Research Involving Prisoners

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Abstract

Background—Given their vulnerability to coercion and exploitation, prisoners who participate in research are protected by Office for Human Research Protections (OHRP) regulations designed to ensure their safety and wellbeing. Knowledge of these regulations is essential for researchers who conduct and institutional review boards (IRBs) that oversee mental health research in correctional settings.

Methods—We explored depth of knowledge of OHRP regulations by surveying a nationwide sample of: (1) mental health researchers who have conducted research in correctional settings; (2) mental health researchers who have conducted research in non-correctional settings; (3) IRB members who have overseen mental health research in correctional settings; (4) IRB members who have overseen mental health research in in non-correctional settings; and (5) IRB prisoner representatives. Participants responded to a 10-item knowledge questionnaire based on OHRP regulations.

Results—1,256 participants provided usable data (44.9% response rate). Results revealed limited knowledge of OHRP regulations, with a mean across groups of 44.1% correct answers. IRB Prisoner representatives, IRB members, and researchers with correctional experience

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demonstrated the highest levels of knowledge; however, even these participants were able to correctly answer only approximately 50% of the items.

Conclusions—Although awareness that prisoners are a protected population and that different regulatory procedures apply to research with them is likely to be universal among researchers and IRB members, our findings reveal limited mastery of the specific OHRP regulations that are essential knowledge for researchers who conduct and IRB members who oversee mental health research in correctional settings. Given well-documented health and healthcare disparities, prisoners could potentially benefit greatly from mental health research; increasing knowledge of the OHRP regulations among researchers and IRB members is a crucial step toward meeting this important public health goal.

Keywords

Prisoners; Ethics Committees; Federal Regulations; Research Oversight; Research Ethics

INTRODUCTION

Estimates suggest that 45% of federal inmates, 56% of state inmates, and 64% of jail inmates – or more than 1.25 million incarcerated individuals in the US – have diagnosable mental health concerns (James and Glaze 2006). Serious mental illnesses (e.g., major depressive, bipolar, and psychotic spectrum disorders) were diagnosed in 14.5% of male and 31.0% of female inmates (Steadman et al. 2009). These rates are over five times the rate of mental health diagnoses in the general community.

Compared to other incarcerated people, inmates with mental illness are significantly more likely to have numerous and serious past-year and lifetime medical conditions and utilize more medical services during incarceration and after release into the community (Cuddeback et al. 2010). Further, prisoners with mental illness (as compared to those without) are more vulnerable to violence and sexual assault while in custody (Crisanti and Frueh 2011; National Prison Rape Elimination Commission 2009; Treatment Advocacy Center 2007); have increased rates of physical illness and injury (Restum 2005); pose a greater suicide risk (Daniel 2006); commit more rules violations during incarceration (James and Glaze 2006); and are more likely to be re-incarcerated (Baillargeon et al. 2009).

These data highlight the need for effective mental health treatment in correctional settings, but due to limited budgets and other priorities, such treatment is only accessed by one in three state inmates, one in four federal inmates, and one in six local inmates (James and Glaze 2006). Low rates of mental health treatment for prisoners are detrimental in that offenders who do receive mental health treatment in prison and during re-integration into the community upon release are less likely to reoffend, have higher rates of employment after release, and experience improved health (Kesten et al. 2012; Pogorzelski et al. 2005). With 600,000 prisoners leaving state or federal prisons annually, and seven million leaving local jails, problems associated with inadequate mental health treatment while incarcerated continue long after inmates have been released and negatively affect their families, friends, and larger communities.

Clearly, correctional settings have a crucial need to improve mental health services. With adequate research safeguards for inmates, prisons can provide an ecologically valid setting to conduct mental health/psychiatric research that addresses the unique needs of these populations. Cislo and Trestman (2013, 304) noted:

... to provide constitutionally mandated medical treatment in an effective manner, evidence is required to establish best practices. Only through well-designed research efforts with prisoners, taking into account their particular population characteristics and contextual contingencies, will it be possible to design and deliver appropriate and informed health services.

A 2007 report commissioned by the Institute of Medicine (IOM), titled *Ethical Considerations for Research Involving Prisoners*, noted that “Research is critically important in providing knowledge needed for informed and enlightened prison policy, as well as for affording health benefits to prisoners” (Institute of Medicine 2007, ix). Research in correctional settings could help inform policymaking and healthcare planning; identify effective and cost-efficient clinical diagnostics and treatment approaches; and improve outcomes for prisoners after release into the community (Cislo and Trestman 2013; Weisburd 2003).

Despite the well-documented need for prison-based mental health studies, research with prisoners has been stymied by historical abuses and maltreatment (Pont 2008). Some of the more egregious examples of abuse include the Holmesburg dermatological experiments that included exposure to dioxin, radiation, and implantation of foreign bodies (Hornblum 1998). Prisoners were susceptible to these and other exploitative research activities due to their vulnerability to coercion, restricted ability to provide informed consent, and threats to privacy and confidentiality.

In response to an outcry over these abuses, beginning in the mid-1970s, new federal regulations set out to provide protections to prisoners involved in research. Although these regulations have served to protect prisoners, they have had the unintended consequence of drastically reducing research conducted in correctional settings (Cislo and Trestman 2013). In effect, the history of research abuse in prison settings in the first half of the 20th century led to the near elimination of research in the latter third of the 20th century and beyond (Hornblum 1997).

Moving forward, it will be beneficial to the wellbeing of prisoners and society to increase the extent and scope of mental health research conducted in correctional settings (Christopher et al. 2011). One step is to expand the conversation initiated by the Institute of Medicine (2007) that spelled out recommendations on how to encourage research while simultaneously increasing protections of prisoners. Another step is to raise awareness of the need for prison-based research and the profound benefits that may accrue to participants and society. A third step is to prepare researchers and IRB members to conduct and oversee correctional research while closely conforming to federal regulations.

The current study contributes to all three of these steps by examining the degree to which researchers and institutional review board (IRB) members have a comprehensive knowledge of the federal guidelines governing research with prisoners.

METHODS

Participants

Data were collected through a larger project funded by the National Institute of Mental Health (NIMH) to examine challenges and barriers to conducting mental health research in correctional settings. For this larger project, participants were sampled from populations of researchers, IRB members, and prisoner representatives via two primary methods.

First, exhaustive searches of electronic databases for grant funding, journal articles, and conference presentations were conducted to identify separate populations of individuals who had conducted mental health and psychiatric research in correctional settings and individuals who had conducted mental health and psychiatric research in other settings. For correctional researchers, the searches included only research conducted in adult correctional settings in the US; for all researchers, searches identified authors with two or more relevant publications or with extramural funding after 2000.

Second, through lists obtained from the Office of Human Research Protections (OHRP) and online searches, we identified populations of IRB members and prisoner representatives. From this group, we first sampled all IRB members and prisoner representatives associated with our population of correctional researchers. We then supplemented these IRB members with a random selection of IRBs and prisoner representatives from OHRP lists to reach our targeted sample size.

Finally, to augment all five groups, we asked individuals who participated in the study to identify other eligible individuals.

Instrumentation

The survey for the overall project consisted of 10 sections: background information; factors associated with informed consent; benefits of research; potential risks of research; justice and fairness; IRB and federal regulations; challenges in conducting mental health research; perceptions and opinions about correctional mental health research; knowledge of federal regulations; and vignettes.

The current study analyzed the knowledge section, which consisted of 10 statements developed and pilot tested by the researchers to assess knowledge of federal rules and regulations for research involving prisoners, namely 45 CFR 46: Subpart C (Department of Health and Human Services 2010). Participants responded to each of these statements by answering “true,” “false,” or “unsure.”

Procedures

This protocol was approved by the IRBs at the University of Alaska Anchorage and Pacific University. Survey procedures followed Dillman's (2007) recommendations.

Survey administration began with a letter notifying potential participants to expect an email requesting their participation in the study. Two weeks later, an email was sent containing a cover letter and link to the informed consent document, payment form, survey, and non-participation form. Code numbers were used to track responses and up to four email reminders were sent at two-week intervals to individuals who had not completed a survey or non-participation form. A letter was mailed one week prior to the final email reminder.

As a safeguard against emails being misidentified as spam and not properly delivered, paper versions of the survey were sent to all potential participants who had not completed the online survey or the non-participation form after the final email reminder.

Respondents who completed either a hardcopy or electronic version of the survey were compensated \$60 for their time.

Statistical Analysis

To calculate a total knowledge score for each participant, correct responses were given one point; all other responses (incorrect, skipped, or unsure) were given zero points.

Preliminary analyses revealed that years of professional experience, gender, and professional employment setting were not related to the total knowledge score; these variables were subsequently excluded from analysis.

Main analysis consisted of a one-way ANOVA to compare knowledge scores across five groups: (1) researchers who conducted mental health research in correctional settings; (2) researchers who conducted mental health research in noncorrectional settings; (3) IRB members who oversaw mental health research protocols in correctional settings; (4) IRB members who oversaw mental health research protocols in non-correctional settings; and (5) IRB prisoner representatives. Duncan's Multiple Range Tests were used as post hoc analyses to determine specific between-group differences.

Data obtained in this study were compared to data from a similar study conducted with HIV/AIDS researchers and IRB members and prisoner representatives who oversee HIV/AIDS research in correctional and non-correctional settings (Johnson et al. 2014). To compare data from these two studies, a 2 (Research Topic: Mental Health, HIV/AIDS) X 5 (Group) ANOVA was calculated and followed up with Duncan's Multiple Range Tests.

RESULTS

Including 349 potential participants identified through snowball sampling, our final sample included 844 correctional mental health researchers, 862 non-correctional mental health researchers, 678 correctional IRB members, 612 non-correctional IRB members, and 311 prisoner representatives. Of these 3,307 potential participants, 436 potential participants were removed due to being deceased, having retired, or having undeliverable addresses, resulting in a final sample of 2,871 individuals. Of these, 1,288 completed our survey, for an overall response rate of approximately 44.9%. Due to having skipped the survey section of interest in the current study, 32 respondents were excluded from this study. Table 1 provides demographic information for the 1,256 participants included in the current study.

Across the five groups, the mean number of items answered correctly was 4.41 of 10 (Standard Deviation [SD] =2.15) or 44.1% correct (see Table 2). The one-way ANOVA revealed significant differences between the five groups' knowledge scores: $F(4,1251)=49.40, p<.000$. Duncan's post hoc analyses demonstrated that IRB prisoner representatives (Mean [M]=5.45, SD=1.56) and IRB chairs and members with correctional experience (M=5.19, SD=1.88) did not differ from one another, but scored significantly higher than the other three groups. Researchers with correctional experience (M=4.46, SD=2.00) and IRB chairs and members without correctional experience (M=4.30, SD=2.16) did not differ from one another, but scored significantly higher than researchers without correctional experience (M=3.09, SD=2.16).

The 2×5 factorial ANOVA revealed a significant main effect for Group: $F(4, 2132)=65.82, p<.000$. Duncan's post hoc analyses for the combined mental health and HIV/AIDS data revealed the same relative order of the five groups' knowledge scores as for mental health data alone, with IRB prisoner representatives having the highest scores (M=5.55, SD=1.64), followed by IRB members with correctional experience (M=5.16, SD=1.79), correctional researchers (M=4.56, SD=1.96), IRB members without correctional experience (M=4.27, SD=2.11), and researchers without correctional experience (M=3.16, SD=2.22). However, for the combined data, post hoc analyses revealed that all five groups differed significantly from each other. No significant main effects for Research Type or Group X Research Type interaction were revealed: $F(1, 2132)=1.59, p=.21$; $F(4, 2132)=0.78, p=.54$, respectively.

DISCUSSION

Federal regulations were developed to provide safeguards to prisoners, a group (along with children, fetuses, and pregnant women) considered particularly vulnerable in the context of research participation. Although not assessed in this study, awareness of this protected nature of prisoners is likely to be universal among researchers and IRB members. However, this study did reveal that detailed knowledge of the OHRP regulations, which is essential for researchers who conduct and IRB members who oversee mental health research in correctional settings, is lacking.

As would be expected, groups who have direct need of this detailed knowledge (i.e., IRB prisoner representatives, IRB members who have reviewed correctional protocols, and researchers who have conducted research in correctional settings) achieved higher scores than researchers and IRB members who conduct or oversee mental health research in non-correctional settings. However, even the three correctional groups were able to answer correctly only about half of the knowledge items.

These findings corroborate those reported by Johnson et al. (2014) from a study that revealed that researchers who conduct and IRB members and IRB prisoner representatives who oversee HIV/AIDS research in correctional settings were only able to answer correctly approximately 50% of knowledge items addressing the same information. The concordance of findings among *mental health* and *HIV/AIDS* researchers and IRB members confirms a lack of knowledge across these groups of professionals that transcends the research topic

(i.e., mental health versus HIV/AIDS) and highlights the need to address the greater knowledge shortfall that has to do with correctional settings.

To apply OHRP guidelines in a manner that truly affords protection to prisoners while maximizing research activity in prisons, information dissemination and understanding must be improved. Although increasing knowledge among *all* researchers and IRB members is a desirable goal, the most pressing targets are IRB members and researchers who oversee or conduct correctional research.

For IRB members, this becomes challenging as most IRBs review prison-based research protocols only infrequently. As a result, IRBs tend to rely upon the IRB chair to be knowledgeable about the regulations given that this is the individual who is responsible for ensuring and documenting conformance with the OHRP requirements. However, given the general lack of knowledge of these regulations among even IRB chairs that have reviewed correctional protocols, it would appear that IRBs need to take greater care to ensure collective knowledge of the guidelines among all members. It is only through such collective knowledge and understanding of information that IRBs can be assured that a research protocol is in strict compliance with OHRP regulations and that prisoners' rights are optimally protected.

Although IRB members are generally required to obtain training on research-related ethics (e.g., through the Collaborative Institutional Training Initiative [CITI; www.citiprogram.org]), such training provides a cursory overview of prison-related regulations and this overview is embedded in a more extensive review of research guidelines. Thus, the information does not in and of itself have specific salience that would lead to better retention. With infrequent reviews of prisoner protocols, retention of knowledge is further threatened.

Options to ensure that information is relayed to IRB members include the distribution of OHRP guidelines prior to reviewing prison-related protocols and specialized refresher training about the guidelines. Translating refreshed knowledge into application, understanding, and operationalization might then be supported further via the development of checklists based on the OHRP guidelines that guide IRB members in the process of applying this infrequently-used knowledge.

It is equally important to broaden the knowledge and understanding of researchers conducting research in correctional settings. Researchers who are interested in working in correctional settings need to master OHRP guidelines and demonstrate that they have prepared their research protocol in strict compliance with the guidelines. It is incumbent on researchers to ensure that their IRB applications are compliant with the guidelines and written in such a manner that it is easy for IRB members to ascertain compliance.

To accomplish this, researchers could be provided with the OHRP guidelines, either directly or made available on their IRBs' websites. The same checklists recommended above for use by IRB members for reviewing prisoner-related protocols could guide researchers' development of IRB applications, including a verification that they have reviewed and understood the guidelines prior to submitting their proposal. In completing the IRB

proposal, the researchers could be asked to structure their applications according to the checklists, not simply checking off compliance with a guideline, but explaining how compliance is achieved and how it operationalizes the spirit of each guideline to consider the special circumstances of a correctional environment and the special vulnerability of the individuals housed in these settings. In that way, the review of an IRB protocol can become a partnership between the IRB and researcher with the common goal of protecting participants.

To improve information dissemination to all relevant parties, one possibility alluded to above is the delivery of specialized workshops and online trainings to educate stakeholders about OHRP guidelines. These workshops could be focused either on being an initial training or a refresher training, with the latter being abbreviated and perhaps more focused on application and operationalization. Both sets of trainings (initial and refresher) could draw on the expertise of experienced IRB members and researchers who have successfully navigated the process.

Additionally, it will be crucial to encourage the incorporation of information about OHRP prisoner protections in ethics, professionalism, and research courses taken during the academic training for individuals likely to conduct or oversee prisoner-related research. Although detailed information about prisoner protections may not be necessary, all of these courses should at least minimally emphasize the additional protections in place for all vulnerable populations.

Continuing education requirements for many of these individuals who have professional licenses are an underutilized resource and could be changed to incorporate OHRP prisoner guidelines, particularly given that such content would likely meet the ongoing ethics training that is required in many jurisdictions. The ultimate goal of these efforts is to ensure that all individuals conducting or overseeing prison research know about the special protections for prisoners, know where to find specific information about them when needed, and have a set of prompts to ensure that regulations are followed in IRB protocols.

One possible benefit of increasing the detailed knowledge of the OHRP regulations is the removal of a possible roadblock to efficient and timely IRB review. That is, on many of the questions, respondents answered in such a way that their response reflected the belief of the existence of more stringent regulations than actually exist, regulations that would be more restrictive and less conducive to research. Greater knowledge of the specifics of the actual regulations and less reliance on the assumption of maximum stringency due to the awareness of prisoners being a protected population may help increase the speed by which research is reviewed and conducted.

Limitations

Several potential limitations must be acknowledged. First, over half of our sample did not complete the survey, raising the possibility of response bias. Second, our questionnaire assessed current knowledge; it may be that this knowledge is not necessary to retain but rather accessed through various avenues when needed.

Third, as no extant questionnaire could be located, we developed our own. Although it was pilot tested, we have not developed validity or reliability data for it. Additionally, although the item regarding expedited review being permissible is correct, OHRP nevertheless recommends full review for all prisoner protocols with the exception of administrative modifications to previously-approved proposals. This fine nuance of not being required but recommended may have accounted for the low average correct response rate (15.3%) for this particular item. Another item regarding control groups could have been read as presenting a double negative, and if so, respondents may have misunderstood the question.

Although this particular item had a relatively high accuracy rate (69.3%), it may have been higher were it not for the possible confusion. Even though we conducted extensive review and pilot testing of the questionnaire, more thorough development (such as the use of cognitive interviews) may have prevented the possible error introduced by these two items.

Although the difficulties with these two items may have contributed to lowered accuracy of responses, their exclusion would still have resulted in an average score across items and groups of only 44.7% instead of 44.1%.

Fourth, although we asked them not to find the answers online but rather only use their current knowledge, participants had access to online resources that could have helped them answer the questionnaire.

CONCLUSIONS

In summary, it is evident from this and prior research (Johnson et al. 2014) that knowledge (and likely practical interpretation) of OHRP guidelines for the ethical and safe conduct of research with prisoners needs to be greatly enhanced. This is particularly true for researchers and IRB members conducting or overseeing prison-based research considering that even these groups responded correctly to only approximately 50% of the knowledge items. Given the well-documented health and healthcare disparities of prisoners and their vulnerability to coercion and exploitation, research in prison settings is important yet challenging (Eldridge et al. 2011). To prepare researchers and reviewers for conducting or overseeing such research, knowledge and understanding of federal regulations represents an essential first step.

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Table 1

Demographic Characteristics of Participants (N=1,256)

Demographic Variable	Number	Percent
Professional Group		
Correctional Researchers	275	21.9%
Non-correctional Researchers	265	21.1%
Correctional IRB Members	309	24.6%
Non-correctional IRB Members	276	22.0%
Prisoner Representatives	131	10.4%
Gender		
Women	668	53.2%
Men	588	46.8%
Race/Ethnicity		
African American	33	2.7%
Asian/Pacific Islander	48	3.8%
Caucasian	1,088	86.6%
Hispanic	39	3.1%
Multiracial	24	1.9%
Native American	1	0.1%
Other	9	0.7%
Missing	14	1.1%
Highest Level of Education		
Less than Master's degree	61	4.9%
Master's degree	164	13.1%
Doctoral or professional degree (including JD, PhD, MD)	1,021	81.2%
Missing	10	0.8%
Age	Mean	Standard Deviation
Years	48.2	11.3

Table 2

Percentage of correct responses by group *

	Prisoner Representative	Correctional IRB Member	Correctional Researcher	Non-correctional IRB Member	Non-correctional Researcher	Total
<i>According to current federal guidelines...</i>						
A non-detained individual on probation or parole in the community can be considered a prisoner. (False)	33.6%	33.0%	28.0%	29.7%	24.2%	29.4%
Continuing IRB review of research protocols that are actively recruiting prisoners as participants requires the presence of a prisoner representative. (True)	92.4%	84.5%	70.5%	76.1%	54.3%	74.0%
A prisoner representative on the IRB must be a prisoner or former prisoner. (False)	96.2%	87.1%	62.9%	73.9%	32.1%	68.2%
If multiple IRBs are reviewing a prisoner research protocol, each IRB must have a prisoner representative. (False)	18.3%	23.9%	24.4%	19.2%	13.6%	20.2%
Research involving prisoners can be reviewed via an expedited review process. (True)	26.0%	22.7%	12.7%	14.9%	4.5%	15.3%
Studies with more than minimal risk to the participants can be conducted with prisoners once approved by the Office for Human Research Protections. (True)	39.7%	51.1%	44.7%	45.3%	39.6%	44.8%
Prisoner research review uses a different definition of "minimal risk" than research that does not include a prisoner population. (True)	43.5%	35.0%	46.9%	30.4%	37.4%	38.0%
Studies with no treatment control groups cannot be conducted with prisoners under any circumstances. (False)	84.7%	77.0%	74.9%	61.6%	55.1%	69.3%

	Prisoner Representative	Correctional IRB Member	Correctional Researcher	Non-correctional IRB Member	Non-correctional Researcher	Total
No member of the IRB (except the IRB prisoner representative) can have any association with the correctional facilities where the research is being conducted, apart from her or his membership on the IRB. (False)	57.3%	46.9%	36.4%	35.1%	23.8%	38.2%
If a research participant becomes incarcerated during the course of a study, the requirements of Subpart C are not applicable since the study is not focused on a correctional sample (e.g., participants are recruited from a drug treatment setting). (False)	53.4%	57.9%	44.7%	43.8%	24.9%	44.5%
Total Correct	54.5%	51.9%	44.6%	43.0%	30.9%	44.1%

* correct answer shown in bold in parentheses