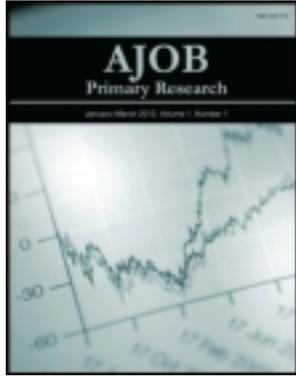


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Moral Stress, Moral Practice, and Ethical Climate in Community-Based Drug-Use Research: Views From the Front Line

Celia B. Fisher ^a, Gala True ^b, Leslie Alexander ^c & Adam L. Fried ^a

^a Fordham University

^b University of Pennsylvania

^c Bryn Mawr College

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Article

Moral Stress, Moral Practice, and Ethical Climate in Community-Based Drug-Use Research: Views From the Front Line

Celia B. Fisher, Fordham University
Gala True, University of Pennsylvania
Leslie Alexander, Bryn Mawr College
Adam L. Fried, Fordham University

Background: The role of front-line researchers, those whose responsibilities include face-to-face contact with participants, is critical to ensuring the responsible conduct of community-based drug use research. To date, there has been little empirical examination of how front-line researchers perceive the effectiveness of ethical procedures in their real-world application and the moral stress they may experience when adherence to scientific procedures appears to conflict with participant protections. **Methods:** This study represents a first step in applying psychological science to examine the work-related attitudes, ethics climate, and moral dilemmas experienced by a national sample of 275 front-line staff members whose responsibilities include face-to-face interaction with participants in community-based drug-use research. Using an anonymous Web-based survey we psychometrically evaluated and examined relationships among six new scales tapping moral stress (frustration in response to perceived barriers to conducting research in a morally appropriate manner); organizational ethics climate; staff support; moral practice dilemmas (perceived conflicts between scientific integrity and participant welfare); research commitment; and research mistrust. **Results:** As predicted, front-line researchers who evidence a strong commitment to their role in the research process and who perceive their organizations as committed to research ethics and staff support experienced lower levels of moral stress. Front-line researchers who were distrustful of the research enterprise and frequently grappled with moral practice dilemmas reported higher levels of moral stress. **Conclusion:** Applying psychometrically reliable scales to empirically examine research ethics challenges can illuminate specific threats to scientific integrity and human subjects protections encountered by front-line staff and suggest organizational strategies for reducing moral stress and enhancing the responsible conduct of research. **Keywords:** ethics, research, substance-related disorders, moral obligations, organizational culture, psychological stress, moral distress

Research is a moral endeavor. Its contribution to science and society rests on meeting the dual obligations of scientific integrity and research participant protections. How to best meet these obligations when working with marginalized and vulnerable groups raises ethical challenges for which the broad language of federal regulations offers incomplete guidance (Fisher 1999; 2004). These obligations are particularly challenging for staff members whose jobs conducting community-based drug use research involve direct contact with participants who are living in poverty, lack adequate health care, are engaged in illegal behaviors, and may come to a research setting during periods of withdrawal or cravings. When designing participant protections, investigators typically draw on their own expertise and the advice of institutional review boards (IRBs) and community advisory boards (CABs). To date, there has been little ethical oversight or empirical examination of the relevance and effectiveness

of scientific and ethical procedures to their real-world application by the staff members employed to implement these procedures. The purpose of this study was to add to the small but growing body of literature on the work-related moral stress, perceptions of ethics climate, and research attitudes of front-line researchers.

FRONT-LINE RESEARCHERS

The role of the front-line researcher is critical to ensuring the responsible conduct of drug use research. In this study, we define front-line researchers as employees whose responsibilities include face-to-face contact with participants through recruitment, enrollment, informed consent, screening, assessment, interviews, direct intervention, or debriefing. They may be drawn from graduate and postgraduate programs or hired for their “insider” knowledge of the neighborhoods from which participants are recruited or

Address correspondence to Celia B. Fisher, PhD, Director, Center for Ethics Education, Fordham University, 441 East Fordham Road—Dealy Hall, Bronx, NY 10458, USA. E-mail: fisher@fordham.edu

their personal history of drug use (Alexander and Richman 2008; True, Alexander, and Richman 2011). Regardless of whether they are drawn from the community or have research-related advanced degrees, they must be able to identify and engage drug users in the communities in which they live, navigate across complex social networks, avoid involvement in participants' illegal behaviors and conflicts with law enforcement, and provide a special cultural competence that can inform the responsible conduct of research (Andrews et al. 2004; Berg et al. 2004; Cunningham et al. 1999; Fisher and Oransky 2008; Hill, Bone, and Butz 1996; Oransky et al. 2009).

Preliminary Work

Little is known about how front-line researchers handle moral tensions that arise when scientific and ethical responsibilities appear to conflict in drug use research. Nor do we know how their perceptions of organizational climate and their own attitudes toward research influence their work-related well-being. As the first phase of a program of research on psychological attitudes and stressors experienced by front-line researchers funded by the National Center for Research Resources (# 1R21RR026302-01), we conducted six planned focus groups (total $N = 36$) of staff involved in direct contact with participants in community-based drug use research in New York City, NY, Hartford, CT, and Philadelphia, PA. A codebook derived from content analysis applied to transcribed focus-group responses yielded .97 agreement across two pairs of raters and indicated themes did not differ across groups. Respondents were strongly committed to their work and perceived their organizations as supportive and committed to the ethical conduct of research. At the same time, they worried about the exploitation of drug users desperate for help and felt burdened by "unrealistic" organizational demands for recruitment and multiple role assignments. They also grappled with stress associated with moral dilemmas, including difficulty protecting participant confidentiality, their inability to provide participants with needed counseling and services, frustration when screening protocols did not reflect real-world drug-use habits, participant attempts to over- or underreport their drug use, concern about consent comprehension, and the effort involved in defending their work against pervasive community research distrust. Finally, their narratives included descriptions of emotional fatigue and fears of burnout (for details see True, Alexander, and Fisher 2012).

Work-Related Moral Stress

The themes expressed in focus groups led us to the moral distress and work-related moral stress literature, which has been almost exclusively studied within the context of nursing, medicine, and humanitarian work (Austin et al. 2007; Corley 2002; Hamric, Borchers, and Epstein 2012; Nilsson et al. 2011). Moral distress, first described by Jameton (1984), occurs "when one knows the right thing to do, but institu-

tional constraints makes it nearly impossible to pursue the right course of action" (6). Based in part on Jameton's definition, Corley and colleagues (2001) constructed the influential Moral Distress Scale, composed of items describing specific moral dilemmas nurses confront in hospital practice. Jameton's (1984) construct of moral distress also included how the moral conflict created by recognition of institutional constraints resulted in frustration, anger, and anxiety. Subsequent research has demonstrated associations between moral distress and job burnout, emotional exhaustion, and job cynicism (Hamric and Blackhall 2007; Hamric et al. 2012; Joseph and Deshpande 1997; Maslach 2003; Schluter et al. 2008; Ulrich et al. 2007; Webster and Baylis 2000). Drawing on later work emphasizing the psychological disequilibrium aspects of Jameton's theory (Wilkinson 1988; Zuzelo 2007), Lutzen and colleagues (2010) developed the Work-Related Moral Distress Questionnaire, which includes items describing both work-related moral conflicts and psychological reactions of practicing nurses.

The construct of work-related moral stress seems particularly relevant to the moral conflicts encountered by front-line researchers who, similar to nurses and their patients, are in constant direct contact with participants. As suggested by our focus-group respondents, work-related moral stress arises following situations in which research staff members must choose between implementing procedures they believe are inadequate or following their own moral conscience in protecting scientific validity or participant welfare.

Organizational Climate

Organizational climate is generally defined as common perceptions of the workplace that influence employee attitudes and behaviors (Schneider 1987). Organizational ethics climate is a subset of this general perception and involves how the organization is perceived to address ethical issues and allow employees to engage in ethical reflection (Brown 1990). Ethics climate has been linked with moral distress and work-related moral stress among nurses (Hamric, Borchers, and Epstein 2012; Hart 2005; Lutzen et al. 2010; Olson 1998; Pauly et al. 2009; Zuzelo 2007). Qualitative studies involving community-based research workers conducting a broad range of studies suggest that lack of organizational ethics training and support may be similarly associated with work-related moral stress among front-line drug-use research staff members (Alexander and Richman 2008; Richman, Alexander, and True 2012; Sunderland et al. 2011; Terpstra et al. 2011; True, Alexander, and Richman 2011).

AIMS OF THE CURRENT STUDY

The primary aim of this research was to begin to focus empirical attention on how work-related psychological attitudes and experiences of front-line staff conducting community-based drug-use research and the organizational climate in which they work affect their levels of moral stress.

To achieve this, we constructed, psychometrically evaluated, and examined relationships among six scales for a Web-based survey designed to test the following hypotheses:

1. Research staff members who evidence a strong commitment to their role in the research process and who perceive their organization as committed to research ethics and staff support will experience lower levels of moral stress.
2. Research staff members who are distrustful of the research enterprise and who frequently grapple with moral practice dilemmas will have higher levels of moral stress.

A secondary aim was to explore the relative salience of specific scale items to illuminate community-based research workers' (CRWs') attitudes and experiences that organizations may need to address to ensure the validity and integrity of the research enterprise.

METHODS

Participants

In 2011, we sent an e-mail to a national sample of 188 principal investigators (PIs) who were described in the National Institutes of Health (NIH) Research Portfolio Online Reporting Tool (RePORT) or the Clinical Trial Network as conducting community-based drug-use research within the last four years. PIs were asked to forward to staff members whose job required direct contact with research participants an e-mail announcement that included a link to a dedicated website describing the study and providing access to the survey. Out of 311 completed surveys, 275 met inclusion criteria: 18 years or older, worked on research involving direct contact with participants in the past 12 months, and did not participate in the preliminary focus-group study. Detailed demographic and employment characteristics are provided in the Results section.

Survey Items and Derived Scales

To our knowledge, moral stress, organizational climate, moral practice dilemmas, and attitudes toward research among front-line researchers in general and those involved in drug-use research in particular have not been quantitatively examined nor studied on a national scale. We therefore developed a set of survey items to assess these factors. Items were drawn from focus-group participant statements (True et al. 2012) and adapted from relevant scales created for health care workers, researchers, and graduate students (referenced in Table 1). A five-member community advisory board (CAB) composed of front-line drug use workers, PIs, and project coordinators met with the investigators to review and reach consensus on 140 items for acceptance, deletion, or revision based on content validity, scale organization, format, clarity, relevance, and participant comfort.

Scale Format

The final set of 110 items was scored on a 4-point Likert-type scale ranging from "strongly disagree" to "strongly agree." Items were organized to comprise six scales: Research Moral Stress Scale (RMSS), Research Ethics Climate Scale (RECS), Organizational Research Support Scale (ORSS), Research Moral Dilemma Scale (RMDs), Research Mistrust Index (RMI), and Research Commitment Index (RCI). Items tapping work-related moral stress were introduced with the stem, "In my most recent or current job on drug use research, I . . ." Items tapping the organizational scales began with the stem "The organization where I currently or most recently worked on a drug use related study. . . ." Based on the CAB members' recommendations, scales tapping moral practice dilemmas, research mistrust, and research commitment began with the following stem:

The statements below are based on opinions expressed in focus groups by CRWs (community-based research workers) involved in drug use and related research studies. For each statement, think about your experiences as a CRW working on studies involving drug use. Check the box that indicates how much you agree or disagree with each statement. There are no right or wrong answers—we are just interested in your experiences and opinions.

Item Analysis and Inter-item Reliability

For each scale, we used the SPSS software's "corrected item total" ($r > .30$) and "alpha-if-item-deleted" calculations to retain items producing the greatest item discriminability and scale internal reliability. Table 1 provides a brief description of the final versions of each scale, including definition of the construct measured, number of original and final number of items, scale reliability, exemplar items, and resources from which items were adapted. Scales are available from the first author upon request.

Additional Measures

The survey began with 26 items covering demographic information and work history. It ended with the 13-item Marlowe-Crowne Social Desirability Scale Short Form (Crowne and Marlowe 1960; Reynolds 1982), a seminal scale measuring the tendency of respondents to answer questions in a socially favorable manner, especially in work or other contexts with high social expectations. In this study, scale scores were applied to statistically control for the effects of social desirability bias in response to other measures.

Procedures

The anonymous survey did not solicit any identifying information, Internet Protocol (IP) addresses were not collected, and the website was constructed with firewall and other security protections to prevent anyone (including the investigators) from linking participants with their responses. The study was approved by the Fordham University IRB and an NIH Certificate of Confidentiality was obtained.

Table 1. Number of items, scale reliability, construct measured, exemplar items, and resources from which items were adapted for each of the six new measures developed for this study

Measure	Construct	Example items	Scale resources
Research Moral Stress Scale (RMSS) • 25 items ^a • Reliability: $\alpha = .89$	Perceived barriers to conducting research in a morally appropriate manner and related feelings of frustration and burnout	“I was emotionally drained at the end of the day.” “I could not provide participants with the service referrals they needed.” “I knew some participants had given false answers to get in the study.”	Maslach Burnout Inventory (Maslach and Jackson 1986) Moral Distress Scale (Corley et al. 2001) Stress of Conscience Questionnaire (Glasberg et al. 2006) Work Related Moral Stress and the Moral Sensitivity Questionnaires (Lütznén et al. 2010) Salvation Army Job Stress Survey (Whiteacre 2006) Lessons from CRWs (True, Alexander, and Fisher 2012)
Research Ethics Climate Scale (RECS) • 13 items (3 reverse scored) • Reliability: $\alpha = .90$	Research organization demonstrates commitment to research ethics through implementation of human subjects protections, staff training and monitoring, team discussions, and procedures for reporting ethical violations	“Had adequate policies to protect participant privacy and confidentiality” “Provided training in research ethics for CRWs” ^b “Encouraged CRWs to discuss their ethical concerns about a study”	Ethical Climate Questionnaire (Filipova 2009) Responsible Conduct of Research–Department Climate Scales (Fisher et al. 2009) Hospital Ethical Climate Survey (Olson 1998) Lessons From CRWs (True et al. 2012)
Organizational Research Support Scale (ORSS) • 16 items (4 reverse scored) • Reliability: $\alpha = .91$	Research organization provides clear expectations for performance, respect for CRW expertise, and sensitivity to CRW job challenges	“Gave CRWs enough information to do their job well” “Included CRWs in recruitment and data collection planning” “Had policies to protect CRW safety on the job”	Research Training Environment Scale–Revised–Short Form (Kahn and Miller 2000) Responsible Conduct of Research–Department Climate Scales (Fisher, Fried, Goodman, and Germano 2009) Lessons From CRWs (True et al. 2012)
Research Commitment Index (RCI) • 6 items • Reliability: $\alpha = .77$	Strong commitment to establishing trusting and responsible research relationships with participants	“It is important that participants trust me.” “It is my responsibility to increase the community’s trust in research.” “I see myself as a bridge between the community and the research organization.”	Lessons From CRWs (True et al. 2012)
Research Mistrust Index (RMI) • 6 items (3 reverse scored) • Reliability: $\alpha = .82$	Lack of trust in investigator intent and the value of research to participants and marginalized communities	“Research exploits drug users who are desperate for help.” “I find participants accepted into the study do not really meet inclusion criteria.” “Drug use related research that is conducted in poor communities will mostly benefit middle class communities.”	HIV Vaccine Trial Trust (Fisher 2010) Lessons From CRWs (True et al. 2012)

Table 1. Number of items, scale reliability, construct measured, exemplar items, and resources from which items were adapted for each of the six new measures developed for this study (Continued)

Measure	Construct	Example items	Scale resources
Research Moral Dilemma Scale (RMDS) •12 items •Reliability: $\alpha = .66$	Behavioral decisions and concerns reflecting moral tension between protecting or promoting participant welfare and adhering to the research protocol	<p>"I find it hard to 'sell' a study to drug users when I do not believe the study will produce useful results."</p> <p>"I discourage drug users from participating in a study if I believe it will not be good for them."</p> <p>"The questions I am told to ask unintentionally give away the drug use inclusion criteria to participants."</p>	<i>Lessons From CRWs</i> (True et al. 2012)

Note. Scales are available upon request from the first author.

^aNumber of items prior to item analysis were 28, 17, 16, 6, 13, and 12 for the RMSS, RECS, ORSS, RCI, RMI, and RMDS, respectively.

^bCRW is the abbreviation for "community researcher worker" and this term was defined for respondents at the beginning of the survey.

Informed consent information was presented on a screen prior to beginning the survey and participants could withdraw (by closing their Web browser) at any time prior to submitting their responses. On completion, participants were led to a webpage that could not be linked with their responses to request an electronic \$40 Amazon.com gift certificate that was e-mailed to them.

Data Analysis Plan

Data analysis began with a calculation of descriptive statistics on demographic and scale scores. To assess response bias, Pearson product moment bivariate correlations between the social desirability scale and the six new scale scores were conducted. To test hypotheses 1 and 2 (see "Aims of the Current Study") relationships among scales were then analyzed through two-tailed partial correlations controlling for social desirability. Next, bivariate correlations between the Research Moral Stress Scale and demographic variables were analyzed and linear regression analysis was performed to determine the relative contribution of the demographic and scale scores to moral stress. Finally, we evaluated the proportion of respondents agreeing with scale statements to illuminate specific challenges to research ethics and scientific integrity.

RESULTS

Demographic and Employment Characteristics

Demographic and employment characteristics are provided in Table 2. The majority of participants were female, self-identified as non-Hispanic white, had received a bachelor's or graduate degree, worked on 2–3 projects during the past 5 years, had at one time lived in the same community in

which they conducted research, and reported a mean age of 35.10 years (standard deviation [SD] = 10.92, range = 20–65). Most participants worked at their position full time, earned more than \$30,000/year, described their financial situation as "just enough to get along," and received health care benefits. All participants had duties involving direct contact with participants; many had overlapping responsibilities. Respondents' work covered a wide range of populations and research methods. Most met with their PI or a supervisor more than once a month.

Means and Correlations Among Scale Scores

Scale means, standard deviations, range, and skewness are provided in Table 3. Consistent with expectations of response bias, all measures were significantly correlated with social desirability. Mean levels of moral stress (RMSS), moral practice dilemmas (RMDS), and research mistrust (RMI) were in the lower "disagree" range of responding (ratings of 1 and 2) and negatively skewed; research ethics climate (RECS), organizational support (ORSS), and research commitment (RCI) scores were in the higher agree range (ratings of 3 and 4) of responding and positively skewed. The pattern of results was the same using transformed or untransformed data. Results are therefore reported using untransformed data.

The results of the partial correlations supported hypotheses 1 and 2 (see Table 3). Research ethics climate (RECS), organizational research support (ORSS), and research commitment (RCI) were significantly and negatively correlated with moral stress (RMSS) and positively correlated with each other. Research mistrust (RMI) and research moral dilemmas (RMDS) were positively correlated with moral stress and with each other. Pearson correlations yielded few significant associations between moral stress

Table 2. Frequency (n) and percent (%) of responses for demographic and employment characteristics (full sample = 275)

	<i>n</i>	%		<i>n</i>	%
Gender			Meeting with PI		
Male	90	32.7%	Never	8	2.9%
Female	177	64.4%	Once or twice	68	24.7%
Transgender	8	2.9%	Once per month	54	19.6%
			More than once per month	145	52.7%
Ethnicity			Hours worked per week		
Hispanic	40	14.5%	35 or more	198	72.0%
African American	33	12.0%	20–34	41	14.9%
White	171	62.2%	10–19	21	7.6%
Other	31	11.3%	Less than 10	15	5.5%
Age (years)			Current salary		
20–29	116	42.2%	<\$5,000–20,000	38	13.9%
30–39	79	28.7%	\$20,001–30,000	38	13.8%
40–49	41	14.9%	\$30,001–40,000	89	32.4%
50 and older	39	14.1%	\$40,001–>\$50,000	95	34.5%
			Decline to answer	15	5.5%
Education			Salary as part of total income		
<4-year college degree	52	18.9%	All	172	62.5%
4-year college degree	121	44.0%	More than half	56	20.4%
Graduate or professional degree	102	37.1%	Less than half	47	17.1%
Years experience			Current financial situation		
1 year or less	64	23.3%	Can't make ends meet	42	15.3%
2–5 years	98	35.6%	Have just enough	163	59.3%
More than 5 years	113	41.1%	Are comfortable	70	25.5%
Drug use studies (past 5 years)			Lived in same community as study participants		
1	64	23.3%	Yes	194	70.5%
2–3	126	45.8%			
4 or more	85	30.9%	Job health benefits		
Personal history of drug use			Yes	215	78.2%
Yes	61	22.2%	Most frequent duties		
Most frequent studies			Individual interviews	231	84.0%
HIV study	177	64.4%	Informed consent	227	82.5%
Survey	184	66.9%	Survey administration	218	79.3%
Harm reduction	131	47.6%	Participant enrollment	194	70.5%
Drug prevention	93	33.8%	Recruitment on street/community	159	57.8%
Medication treatment	78	28.4%	Recruitment within health care center	158	57.5%
Counseling treatment	78	28.4%	Most frequent participants		
Most frequent drugs			Person who injects drugs (PWID)	221	80.4%
Cocaine	246	89.5%	Unemployed		
Alcohol	243	88.4%	Homeless	230	83.6%
Marijuana	240	87.3%	HIV+	213	77.5%
Heroin	221	80.4%	Men who have sex with men	190	69.1%
Crack	213	77.5%	Sex worker	172	62.5%
Pharm opiate	207	75.3%	Mentally ill	159	57.8%
Methamphetamine	200	72.7%		158	57.5%
Street methadone	178	64.7%			

Table 3. Means, standard deviations (SD), and partial correlations (controlling for social desirability) among scale scores

	Scales					
	RMSS	RECS	ORSS	RCI	RMI	RMDS
Descriptive statistics						
Mean	1.89	3.17	3.08	3.24	1.81	1.71
SD	.45	.46	.57	.52	.63	.39
Range ^a	1.00–3.24	1.38–4.00	1.19–4.00	1.33–4.00	1.00–4.00	1.00–3.17
Standard Score of Skewness ^b	2.65	–7.14	–3.54	–5.92	4.23	1.63
Correlations						
Social Desirability Scale	–.22***	.12*	.12*	.12*	–.24***	–.13*
Research Moral Distress Scale (RMSS)		–.71***	–.72***	–.16**	.70***	.47***
Research Ethics Climate Scale (RECS)			.76***	.24***	–.62***	–.35***
Organizational Research Support Scale (ORSS)				.11	–.56***	–.32***
Research Commitment Index (RCI)					–.18**	.14*
Research Mistrust Index (RMI)						.53***
Research Moral Dilemma Scale (RMDS)						

^a Possible range for all scales 1–4.

^b Standard score of the skewness was calculated by dividing the skewness value by the standard error of skewness.

Note. Partial correlations were conducted controlling for social desirability.

* $p \leq .05$; ** $p \leq .01$; *** $p \leq .001$.

and demographic and employment characteristics. With the exception of age ($r = -.23, p < .001$) and frequency of meeting with the PI ($r = -.23, p < .001$), no other demographic variables (i.e., educational level, living in the research community, personal history of drug use) were significantly related to the moral stress scale.

Multiple Regression

Demographic and scale scores significantly correlated with moral stress were included in the multiple regression with one exception. To reduce potential multicollinearity produced by the high correlation between the two organizational climate scales (RECS and ORSS), only the RECS was included. Data were entered in two consecutive blocks. Block 1 controlled for the influence of social desirability and demographic variables. Block 2 included the RECS, RCI, RMI, and RMDS (see Table 4). The range of tolerance (.97–.65) and variance inflation factor (VIF) (1.03–2.18) scores met criteria for acceptable collinearity (Tabachnick and Fidell 2007). The full model R^2 accounted for 69% of variance. Beta values in block 2 indicated that age and scales measuring ethical climate, research mistrust, and research moral dilemmas continued to independently contribute to moral stress when other variables were held constant. Social desirability, frequency of meetings with the investigator,

and research commitment were no longer significant in the final model.

Item Salience

To examine the salience of individual items, we defined endorsement as a response of 3 = “somewhat” or 4 = “very likely to agree” with a statement. As illustrated in Table 5, despite the social desirability bias, 30% to more than 60% of participants endorsed statements on the RMSS indicating work-related moral stress and on the RMDS indicating behavioral decisions prioritizing participant protection and well-being over the research protocol when these dual obligations were perceived to conflict. Research mistrust scores were relatively low, although 51% of respondents endorsed two or more items on the six-item RMI.

Overall, respondents rated their organizations highly on research ethics climate and organizational research support. Items with the lowest endorsement (68–75%) on the RECS pertained to discussions with and policies relevant to CRWs’ ethical challenges and community dissemination of research results. Items with the lowest endorsement (57–62%) on the ORSS pertained to counseling for CRWs who experienced trauma on the job, realistic expectations regarding recruitment numbers, and assignment of CRWs to multiple roles. Research commitment was similarly high.

Table 4. Social desirability, demographic variables, organizational ethical climate and research support, research commitment, research mistrust, and moral practice dilemmas regressed onto moral distress^a

		<i>R</i> ²	<i>F</i> Change	<i>β</i>	<i>t</i>
Block 1	Response bias and demographics	.13	13.02***		
	Social desirability			-.19	-3.34***
	Age			-.16	-2.77**
	Frequency meetings with investigator			-.21	-3.65***
Block 2	Research ethics scales	.69	96.61***		
	Social desirability			-0.05	-1.27
	Age			-0.06	-2.18*
	Frequency of meetings with investigator			-0.03	-0.83
	Research ethics climate			-0.42	-8.61***
	Research commitment			-0.00	-0.99
	Research mistrust			0.36	6.63***
Research Moral Dilemma Scale	0.13	2.80**			

^a Durbin-Watson = 2.02.
p* ≤ .05; *p* ≤ .01; ****p* ≤ .001.

Implications of the salience of scale items to staff work-related stress, work climate, and the responsible conduct of research are discussed next.

DISCUSSION

This study represents a first step in using psychometric scale construction techniques to draw empirical attention to attitudes and moral tensions experienced by a national sample of front-line staff conducting community-based drug-use research and how these factors and the organizational climate in which they work are associated with work-related moral stress and the validity and integrity of the research enterprise. It also extends the use of quantitative measures of work-related moral stress, previously limited to health care workers, to the experiences of research staff members. This section begins with a summary of what we learned about the demographics of this population, followed by discussion of the general nature of and relationship among their moral research resources and risks. We then turn to the limitations of the study and conclude with a discussion of steps investigators can take to reduce the stressful nature of front-line work and safeguard the responsible conduct of research.

Who Are the Front-Line Researchers?

There is currently no database documenting the demographic characteristics, qualifications, and job responsibilities of front-line researchers working on federally funded drug use research (National Institute on Drug Abuse 2010, personal communication). Our national survey thus provides some insights into the characteristics of individuals responsible for the implementation of this important work. First, while small sample qualitative studies have focused on staff drawn from the community for their insider

knowledge (Alexander and Richman 2008; Andrews et al. 2004; Berg et al. 2004; Hill et al. 1996; Nilsson et al. 2011; Richman et al. 2012; Sunderland et al. 2011; Terpstra et al. 2011; True et al. 2011), in our survey a majority of respondents were college educated and many held graduate degrees. Regardless of educational status, 70% had lived in communities in which they conduct research and a quarter reported a personal history of drug use.

The majority of respondents were involved in obtaining informed consent, enrollment and intake, and conducting interviews; half engaged in recruitment; and approximately one-third had responsibilities related to harm reduction training, focus groups, and debriefing. Most took on multiple roles. Interestingly, demographic and job-related factors had little association with differences in responses to scales assessing moral stress, perceived organizational climate, or research attitudes. This suggests that the context and nature of front-line community-based drug use research itself have a powerful effect on front-line staff attitudes and experiences above and beyond individual characteristics.

Organizational Climate and Research Commitment

Organizational policies create the climate in which research integrity among staff flourishes or flounders (Fisher, Fried, and Feldman 2009). Respondents met frequently with their principal investigator and perceived their organizations as dedicated to research ethics and providing clear performance expectations. However, consistent with our focus-group findings and previous qualitative studies (Alexander and Richman 2008; Richman, et al. 2012; True et al. 2011), approximately 40% endorsed items indicating their organization did not provide counseling for job-related stress

Table 5. Frequency (*n*) and percent (%) of items receiving the highest levels of endorsement on the Research Moral Stress Scale, Moral Practice Dilemmas Scale, and Research Mistrust Index

Scale	<i>n</i>	%
Research Moral Stress Scale (RMSS)		
I was emotionally drained at the end of the day.	155	56%
I knew some participants had given false answers to get into the study.	155	56%
I did not believe some participants really understood the research they agreed to participate in.	150	54%
This job was stressful.	143	52%
I believed that offering money made some participants ignore the risks of the research.	125	45%
I worried the job was hardening me emotionally.	112	41%
I was over-burdened by the demands of my job.	98	36%
I could not provide participants with the service referrals they needed.	100	36%
I could not correct a problem in how the research was conducted.	95	34%
I believed the research screening criteria excluded people who should be in the study.	86	31%
Research Moral Dilemma Scale (RMDS)		
I won't go out to 'sell' a study to drug users if I don't trust the investigator.	184	67%
I find it hard to 'sell' a study to drug users when I do not believe the study will produce useful results.	118	43%
Even when it is not part of my job I counsel participants about their drug problems.	107	39%
I discourage drug users from participating in a study if I believe it will not be good for them.	101	37%
The questions I am told to ask unintentionally give away the drug inclusion criteria.	96	32%
I use my own money to buy coffee or other small goods to keep drug users interested in participating.	85	31%
I exclude drug users from participating if I believe they are lying about which drugs they use.	83	30%
Research Mistrust Index (RMI)		
Most investigators do not care about participants; they just want to get the study done.	84	30%
Drug users in poor communities are paid less for being in a study than middle class drug users.	72	26%
Drug use related research that is conducted in poor communities will mostly benefit middle class.	63	23%
Research exploits drug users who are desperate for help.	61	22%

and had unrealistic demands for recruitment numbers and multiple staff role assignments. As predicted, a positive organizational climate was associated with a strong research commitment and with lower levels of moral stress, research mistrust, and moral practice dilemmas. The link between organizational climate and moral distress and work-related moral stress is consistent with research involving nurses (Hamric et al., 2012; Hart 2005; Lutzen et al. 2010; Olson 1998; Pauly et al. 2009; Zuzelo 2007).

Moral Stress, Research Mistrust, and Moral Practice Dilemmas

Although levels were not high, approximately half of the respondents experienced at least modest levels (scores in the "somewhat agree" range) of moral stress. More than one-third felt overburdened by job demands. Some concerns were related to challenges implementing human subjects protections. For example, many endorsed statements

indicating concern that participants did not fully understand the informed consent or ignored research risks when money was offered. The findings that research staff members experience moral distress are consistent with perceptions of research supervisors reported by Sunderland and colleagues (2011).

Responses also provide insight to potential threats to scientific validity. At least one-third of respondents expressed unease about what they perceived to be the lack of external validity of the inclusion criteria they were required to use and indicated participants often gave false information about their drug use. Respondents also endorsed statements describing their inability to correct problems in how research was conducted and to provide participants with needed referrals. Moreover, despite the protective influence of exemplary organizational factors, 30% agreed with the statement on the research mistrust index, "Investigators do not care about participants, they just want to get the study done."

Given these concerns and those relating to organizational pressures, it is disconcerting but perhaps not surprising that when there is a perceived conflict between adhering to a research protocol and protecting or caring for participant needs, many front-line researchers favor the latter. At least 30% reported that they would actively discourage participation or simply not "sell" a study if they did not trust the investigator or if they believed the research would not benefit participants. They also took it on themselves to eliminate participants they believed were lying to get into a study, to counsel participants about their drug use outside the research protocol, and to use their own money to buy small goods to increase recruitment. These decisions reflect a threat to scientific validity of which many investigators may be unaware.

Strengths and Limitations

A strength of this study is our recruitment for the first time of a large national sample of front-line research staff. Although many PIs e-mailed to let us know they had forwarded the announcement to staff, we did not ask them to report how many staff members they had e-mailed. Thus, given the absence of a national database, the representativeness of the sample in terms of response rate and demographic and job characteristics is unknown. For example, a majority of respondents were non-Hispanic white and highly educated. Although the sample sizes were large enough to test influences of ethnicity and education on moral stress (which were not significant), we cannot reject the individual or joint influences of these factors with confidence.

A second strength of the study was the construction of scales evidencing good content and construct validity and internal reliability. However, they must be viewed as preliminary and subjected to replication and additional psychometric evaluation on new samples. For example, some of the scales were highly correlated, which brings into question the discriminant validity of these measures. In addition,

the inter-item reliability of .66 for the moral practice dilemmas (RMDS) is just below the commonly accepted threshold of .70 for a new scale (George and Mallery 2003). Further testing may yield a higher alpha score.

Finally, as with all anonymous, Web-based, self-report studies, this survey cannot confirm the status of respondents and is vulnerable to inaccurate response rates based on poor recall or response bias. Indeed, our scales were correlated with social desirability, and as a result of ceiling and floor effects, the scales may not have captured the full range of opinions. However, hypothesis-testing controlling for the effects of social desirability confirmed the predicted relationships among scales, providing confidence in the validity of response patterns.

Conclusion

Many of the ethical challenges faced by researchers can be understood in terms of the "scientist-citizen dilemma" (Fisher and Rosendahl 1990; Veatch 1987). This dilemma arises from researchers' dual moral obligation to produce scientifically valid knowledge and at the same time protect the rights and welfare of research participants (Fisher and Goodman 2006). While principal investigators confront this dilemma in the design of research methods and human subjects protections, front-line research staff members engaged in the "practical process of moral agency" (Lutzen et al. 2010, 214) may encounter them on a daily basis. Our research suggests that front-line staff members experience moral stress when they cannot actualize these dual values via their work and that a supportive organizational climate can reduce this stress.

This study has taken a first step in drawing empirical attention to the attitudes and experiences of a national sample of front-line staff conducting community-based drug use research. Our data provide a psychological portrait of community-based front-line researchers strongly committed to their work, to implementing good science, and to protecting the rights and wellbeing of research participants. This portrait also includes a positive perception of research organizations as committed to and responsibly implementing procedures to ensure staff competence, scientific integrity, and human subjects protections.

At the same time, our data suggest that working in an ethically responsible and supportive organization does not by itself reduce challenges in the field. The nature of community-based drug use research places staff members in daily contact with social injustices experienced by the marginalized populations with whom they work. They also have firsthand experience with real-world constraints on the implementation of research ethics procedures, the external validity of research protocols, and the harms and goods of participation to individual participants. Thus, front-line researchers experience moral stress when they find themselves in situations in which they perceive that adhering either to scientific integrity or to social justice requires abandoning one or the other ideal.

Implications for Organizational Policies

This study provides an empirical foundation for steps principal investigators might consider to further promote front-line research work. First, staff members have valuable and unique expertise in the challenges of community-based drug-use research, including the informed consent preparedness and intervention needs of the community, barriers to recruitment, and limitations of inclusion/exclusion criteria reflecting the real-world lives of street drug users in the community. Investigators may be able to avoid some of the implementation problems in recruitment and informed consent noted by our respondents by drawing on this expertise at the point where ethical procedures are being developed.

Once the research has begun, regular team meetings may benefit from direct questions regarding how staff experience the adequacy of informed consent procedures, unanticipated recruitment challenges, the effect of monetary or other incentives on participation, and suggestions for modifications to procedures that might reduce research mistrust. The data suggest that frequent, ongoing, and open dialogue with research staff members on ways to reduce the stressfulness of their job is equally important to supporting the responsible conduct of research. These include a climate in which front-line researchers feel free to discuss whether job expectations (i.e., recruitment pressures, multiple role responsibilities) are realistic and fair and whether their safety and counseling needs are being adequately met, and are given the opportunity to reflect on the scientist-citizen dilemma and how moral practice dilemmas might be anticipated and resolved.

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The article has been read and approved by all authors. Each author participated sufficiently in the work to take public responsibility for the content, including conception and design, analysis and interpretation of data, and revising the article critically for important intellectual content.

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COMPETING INTERESTS

None declared.

ETHICAL APPROVAL

This study was approved by the Fordham University IRB.

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