

ILLICIT DRUG USERS ARE INTERESTED AND WILLING TO PARTICIPATE IN
HEALTH RESEARCH

By

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Abstract of Thesis Presented to the Graduate School
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Although illicit drug use is common in the United States, drug users are often excluded from health research studies. In order to increase the participation of drug users in research, their attitudes and preferences about research need to be understood. As part of a NIDA-funded study, we compared Current Drug Users (CDUs; defined by use of cocaine or crack, marijuana, heroin, speed or amphetamines, inhalants, or hallucinogens in the past 12 months), Past Drug Users (PDUs; use not in the past 12 months), and Never Drug Users (NDUs) on their perceptions of and attitudes toward research participation, remuneration, coercion, exclusion, and uncommon informed consent practices. A total of 614 participants (313 current drug users, 162 past drug users, and 139 never drug users) were enrolled through the CTSA and HealthStreet funded community-based recruitment model. Despite being less likely than PDUs and NDUs to have participated in research (27% PDU vs 28% NDU vs 18% CDU), CDUs were more willing than NDUs to participate in a health study where they had to give a blood sample (93% CDU vs 85% NDU; $p = 0.0069$), stay overnight in a hospital or clinic (84% CDU vs 73% NDU; $p = 0.0064$), or allow a researcher to see their medical records

(93% CDU vs 85% NDU; $p = 0.0045$). Drug use groups did not differ on what they considered a fair amount of remuneration; three-fourths (75%) of all participants were willing to participate if unpaid ($p = 0.14$). Given that some states are approving legal medical and recreational marijuana, Principle Investigators will need to make inclusion decisions about whether those with a history of marijuana use can be included.

Findings show that current drug users are interested in participating in health research and can be included.

CHAPTER 1 INTRODUCTION

According to the Substance Abuse and Mental Health Services Administration (SAMHSA, 2013), 9.4% of Americans used illicit drugs in the past month, a percentage which has increased over the past 7 years. This percentage will likely continue to grow with the legalization of medical and recreational marijuana. Although drug use is common in America, this population is often excluded from health research studies (Okuda et al., 2010; Blanco et al., 2008; Humphreys et al., 2008). Exclusion criteria are appropriate and even necessary when used to enhance patient welfare and optimize internal validity (Humphreys et al., 2005). However, excessively narrow inclusion and unjustified exclusion criteria are commonplace (Schmidt et al., 2014; Van Spall et al., 2007) and limit generalizability of findings, as they skew study populations and bias outcomes (Humphreys et al., 2008; Westen and Morrison, 2001). Okuda and colleagues (2010) found that 80% of their sample of 133 community individuals with cannabis dependence would be excluded from participating in clinical trials solely as a result of their drug use disorder. Humphreys and colleagues (2008) found that drug use exclusions produced a large downward bias in Addiction Severity Index (ASI) alcohol composite scores in one sample and a moderate upward bias in another sample.

Webb et al. (2015) found that African American's (AAs) who were currently using cannabis or who had used cannabis in the past were just as interested and willing to participate in research as their AA peers who had never used cannabis. When assessing willingness to participate, researchers assume potential participants are considering what their participation will entail. Some studies have considered how users' attitudes towards specific types of research participation differ. Strickland and

Stoops (2015) found that cocaine users viewed most research practices as no more risky than everyday life. They rated “taking an experimental medication” as the most risky research activity, but still did not find it riskier than what they would encounter in everyday life (Strickland and Stoops, 2015). Furthermore, despite having some reservations about the confidentiality of their data, drug users in six focus groups all mentioned being willing to undergo genetic testing to improve HIV, HCV, and addiction care (Perlman et al., 2015).

Some researchers feel that increased participation and retention of drug users is only attainable through the use of large amounts of compensation, yet this is often viewed as unethical with drug using populations (Striley, 2011). However, various populations of drug users have been successfully retained over time without the use of large incentives (Dennis et al., 2003; Scott et al., 2003; Cottler et al., 1996). Some researchers are hesitant to compensate drug users with cash for fear that it might be used to buy drugs. Nonetheless, research has shown that neither the magnitude nor the mode of remuneration has a significant effect on rates of new drug use or perceptions of coercion (Festinger et al., 2005; Festinger and Dugosh, 2012). Furthermore, when compared with coupons, cash has been found to be more valued and less stigmatizing (Cottler et al., 1995) and it can improve retention without increasing the acquisition of drugs or contraband (Festinger and Dugosh, 2012).

Compensation must neither be too high, so as to be coercive, nor too low, so as to be exploitative. As there is little consistency across institutions and no formal IRB policy in determining appropriate remuneration, it is important to know what drug users deem appropriate for hypothetical studies in which they might enroll. We recently found

(Webb et al., 2015) no significant difference between current AA cannabis users and AA never users on how much they perceived as a “fair amount” for a hypothetical study. It is important to know if this finding extends to other races and populations of drug users.

Drug users need to be included in all types of health research for findings to be applicable to them. In order to effectively increase the participation of current drug users in health research, we need to know if they differ from non-drug and past drug users in their opinions and preferences about the research process. We applied for a NIDA (National Institute on Drug Abuse) grant to establish partnerships with the NIH Clinical and Translational Science Awards (CTSA) to integrate drug abuse epidemiology research and build an extension to our community engagement program to increase community member participation in research. Building off of our recent findings (Webb et al., 2015) among African-American marijuana users only, data from the NIDA-funded study, “Transformative Approach to Reduce Research Disparities Towards Drug Users” (also called the Navigation Study, LB Cottler PI) were examined for differences in attitudes and perceptions between Current Drug Users (CDUs), Past Drug Users (PDUs) and Never Drug Users (NDUs) toward participation in research, payment for research, coercive remuneration, exclusion from research, and practices of informed consent.

CHAPTER 2 METHODS

Participants were recruited for the Navigation Study from 2012 to 2014 through HealthStreet, a CTSA and NIDA funded community-based outreach model used to connect underrepresented populations with appropriate research opportunities and needed medical and social services. HealthStreet was originally founded by Dr. Linda Cottler at Washington University in St. Louis and was opened at the University of Florida in Gainesville in 2011 as part of the UF CTSI. HealthStreet aims to diversify research populations by giving traditionally underrepresented groups like racial and ethnic minorities, women, drug users, the elderly, and others a chance to participate.

Community Health Workers, or CHWs, are trusted and trained community members who promote the public's voice and increase health awareness through outreach and community health education. HealthStreet CHWs meet with Gainesville community members at locations such as laundromats, bus stops, churches, shelters, libraries, and health fairs and describe the purpose of HealthStreet. Interested individuals are then consented to participate in HealthStreet and a Health Intake Form is administered. The Health Intake Form is used by the CHWs to gather locating information, top health and neighborhood concerns, health conditions, drug use, past research experience, and willingness to participate in different types of research. Individuals are linked to relevant research studies at the University of Florida using information collected from the Health Intake Form (Cottler et al., 2011).

In order to be linked with the Navigation Study, individuals had to be between the ages of 18 and 80, provide at least two forms of contact for follow-up, and live in a one county area in North Central Florida. Individuals who were interested and met criteria

were linked by CHWs in the field. Contact information for those linked in the field was then given to the Navigation team and they called the linked individuals to further describe the study and set up a time for a baseline interview. A total of 614 eligible and willing individuals completed the baseline interview between 2011 and 2013. The interview took about 60 minutes

Instruments Used In Analysis

Data for the following analyses comes from the Navigation Study instruments: the Substance Abuse Module – 12 Month (SAM-12M; Horton et al., 2000) and the Ethics in Sensitive Research Attitude Assessment (ESRAA; DuBois, O’Leary and Cottler, 2009). The analyses also include data from each participant’s HealthStreet Health Intake Form.

Drug Use Status

Participants who endorsed use of cocaine or crack, marijuana, heroin, speed or amphetamines, inhalants, or hallucinogens in the past 12 months during administration of the SAM-12M (Horton et al., 2000) were classified as Current Drug Users (n=313). Most (76%) of those classified as Current Drug Users met criteria as a result of using illicit substances in the past 30 days.

Since the SAM-12M does not capture lifetime use of substances, questions from the HealthStreet Health Intake Form were additionally used to determine whether a participant was a Past Drug User (more than 12 months ago) or a Never Drug User. Those who endorsed ever using cocaine or crack, marijuana, heroin, speed or amphetamines, inhalants, or hallucinogens on the HealthStreet Health Intake Form were classified as Past Drug Users (n=162). Those who did not endorse lifetime use of

any illicit drugs on the HealthStreet Health Intake Form were classified as Never Drug Users (n=139).

Research Participation and Interests

Participants were asked if they had “ever been in a health research study.” Responses were grouped as “Yes” and “No/Not Sure.” They were also asked if they would volunteer for any of eight different types of health research studies: those that only asked questions about health, medical record review, giving a blood sample, giving a sample for genetic studies, taking medicine, staying overnight in a hospital or clinic, using medical equipment, and research participation for no pay. Possible answers were “Yes” and “No.” In addition, participants were asked how interested they were in being in a research study. Responses were “Definitely,” “Maybe,” or “Not at all.” For analysis, these responses were grouped as “Definitely” or “Maybe/Not at all.”

Perceptions of Fair Remuneration, Coercion, and Exclusion

Opinions regarding remuneration, coercion, and exclusion were gathered through Ethics in Sensitive Research Attitude Assessment (ESRAA; DuBois, O’Leary and Cottler, 2009). Participants were asked if research participants should be paid for their time, if it is fair that some researchers are not allowed to pay drug users cash, what would be a “fair amount” of payment for a 1.5 hour study with an interview and a blood test, and if they would participate in that study if offered a gift card instead of that “fair amount” in cash. ESRAA also elicited information about coercive remuneration: what would be “a lot” of money for that same hypothetical study, if they would participate in a study if offered a gift card for “a lot amount” instead of “a lot amount” in cash, if “a lot” of money would make them sign up for a study they normally would not sign up for, if they would ignore the risks of a study if they were paid “a lot” to participate, and if

researchers should be allowed to offer “a lot” to get people to sign up for a study. Participants were also asked if it was fair for researchers doing studies on high blood pressure, diabetes and HIV to often exclude people who were drug users. Responses were coded as “Yes,” “No,” “Don’t Know,” or as a dollar amount as appropriate. Conservatively, for the purposes of this analysis, all “Don’t Know” responses to ESRAA questions were recoded “No.”

Informed Consent Preferences

Preferences regarding uncommon informed consent practices were also gathered through Ethics in Sensitive Research Attitude Assessment (ESRAA; DuBois, O’Leary and Cottler, 2009). Participants were reminded that they had completed an informed consent process before they could participate in the present study and that the purpose of informed consent was to make sure that research participants understood what would happen if they agreed to participate in a study. Participants were then asked if they were to participate in another study, would they 1) want the researcher to read the whole informed consent out loud to them, 2) want to be asked questions to be sure they understood the study, 3) want researchers to make sure they weren’t high, and 4) want researchers to remind them of what they agreed to do at every study visit. They were also asked if they would want a friend, family member, or stranger advocate with them when they were consenting. Additionally, they were asked if they would rather give their consent verbally than in writing. Responses were coded as “Yes” or “No.”

Sample and Statistical Methods

Chi-square tests and ANOVAs were calculated by drug use status for demographics and attitudes and perceptions of research participation, remuneration,

coercion, exclusion, and informed consent. Responses to the two questions from ESRAA examining fair and coercive compensation for a 1.5 hour study including an interview and a blood test were not normally distributed. Categories were created based on the interquartile ranges of the data and then chi-square tests were calculated to see if there were differences in distribution by drug use status.

CHAPTER 3 RESULTS

Overall Sample Demographics

Among the sample of 614 participants, about 53% identified as Black, Non-Hispanic, 38% as White, Non-Hispanic, and about 9% as some other race/ethnicity (“Other”). The average age was 43, with a range from 18 to 77. A majority of participants were married (49%) and had at least a high-school equivalent education (82%). About half were employed (51%), had some type of medical insurance (52%), and considered themselves to be in excellent or good health (52%). More than half smoked cigarettes (55%) or drank alcohol (73%) in the last year.

Results by Drug Use Status

CDUs were significantly more likely than PDUs and NDUs to be male (57% CDU vs 44% PDU; $\chi^2(1, n=475) = 5.9151, p = 0.0150$) (57% CDU vs 34% NDU; $\chi^2(1, n=452) = 18.2698, p < 0.0001$); never married (56% CDU vs 38% PDU; $\chi^2(2, n=475) = 15.9842, p = 0.0003$) (56% CDU vs 47% NDU; $\chi^2(2, n=452) = 9.6169, p = 0.0082$); cigarette smokers in the past 12 months (71% CDU vs 54% PDU; $\chi^2(1, n=475) = 14.4904, p = 0.0001$) (71% CDU vs 22% NDU; $\chi^2(1, n=452) = 96.3373, p < 0.0001$) and drinkers in the past 12 months (86% CDU vs 66% PDU; $\chi^2(1, n=475) = 26.6336, p < 0.0001$) (86% CDU vs 49% NDU; $\chi^2(1, n=452) = 71.1624, p < 0.0001$). CDUs were also significantly less likely than NDUs to be medically insured (46% CDU vs 63% NDU; $\chi^2(1, n=452) = 10.5937, p = 0.0011$), to have a college degree (14% CDU vs 38% NDU; $\chi^2(2, n=452) = 33.6775, p < 0.0001$), and to have good/excellent self-perceived health (49% CDU vs 64% NDU; $\chi^2(1, n=452) = 8.8780, p = 0.0029$). Age was significantly different between drug use groups ($F(2, n=614) = 7.33, p = 0.0007$); post hoc

comparisons using the Tukey Test revealed that CDUs were significantly younger than PDUs ($p = 0.0007$). There were no significant differences between drug use groups in race or employment status.

The most prevalent drug used by the majority of CDUs (94%) in this sample was marijuana followed by crack/cocaine (20%); club drugs and hallucinogens were reported by 5-8% of the CDUs. Similarly, 90% of the PDUs had used marijuana and the second most frequently used drug was crack/cocaine (46%). A sizeable proportion of PDUs also reported past use of speed or amphetamines (18%) and hallucinogens (14%) (data not shown in Table 1).

When compared to both NDUs and PDUs, CDUs were less likely to have been involved in past research (18% CDU; 27% PDU; 28% NDU; $\chi^2 (2, n=610) = 6.7611, p = 0.0340$). There were statistical differences between CDUs and NDUs on willingness to volunteer for 3 types of studies. CDUs were more willing than NDUs to volunteer for a study that required authorizing researchers to see medical records (93% CDU vs 85% NDU; $\chi^2 (1, n=452) = 8.0553, p = 0.0045$), giving a blood sample (93% CDU vs 85% NDU; $\chi^2 (1, n=452) = 7.2986, p = 0.0069$), and staying overnight in a hospital or clinic (84% CDU vs 73% NDU; $\chi^2 (1, n=452) = 7.4245, p = 0.0064$). PDUs were more willing than NDUs to volunteer for a study that required staying overnight in a hospital or clinic (85% PDU vs 73% NDU; $\chi^2 (1, n=301) = 6.4079, p = 0.0114$) and giving a genetic sample (94% PDU vs 86% NDU; $\chi^2 (1, n=301) = 5.6272, p = 0.0177$). There were no differences by drug use status in willingness to volunteer for studies that required using medical equipment, taking medication, only asked health questions, or did not offer remuneration. A study that only asked questions about health was most desirable

(96% of CDUs and NDUs and 95% of PDUs would volunteer; $p = 0.85$) and a study where one might have to take medication was least desirable (72% of CDUs, 69% of PDUs, and 62% of NDUs would volunteer; $p = 0.10$). Overall, 75% of participants would volunteer for a study that was not paid. When asked which of these 8 types of studies they would be willing to volunteer for, 48% of CDUs and 49% of PDUs said they were willing to volunteer for all eight options, compared to only 35% of NDUs ($\chi^2(2, n=610) = 8.6122, p = 0.0135$; not shown in Table 2).

When asked questions about fair payment, participants tended to agree with each other regardless of drug use status. The majority of participants (90%) thought that respondents should be paid for their time ($p = 0.18$). There was no statistical difference by drug use status on what participants considered a fair amount of compensation for a 1.5 hour study with an interview and a blood test. The median response for the sample was \$30. Both CDUs and NDUs ranged in responses from \$5 to \$500 and PDUs ranged in responses from \$0 to \$250. Respondents overwhelmingly reported (98%) that they would still participate in a study if they were offered a gift card instead of cash for the amount they considered “fair.” There was some disagreement, however, on the topic of paying drug users cash for participation; 83% of PDUs and 86% of NDUs thought it was fair that researchers not be allowed to give drug users cash, compared to only 72% of CDUs ($\chi^2(2, n=614) = 11.9794, p = 0.0025$).

When asked questions about coercive payment, participants gave similar responses despite drug use group. Participants did not differ in what they considered “a lot” of payment for a 1.5 hour study with an interview and a blood test ($p = 0.36$). The median amount deemed “a lot” by the sample was \$100. Again, current drug users,

past users, and non-users overwhelmingly agreed (97%) that they would still participate in a study that offered a gift card instead of cash for the amount they considered “a lot.” About half the participants (47% overall; 45% CDUs, 53% PDUs, 46% NDUs; $p = 0.17$) said that “a lot” of money would make them sign up for a study they normally wouldn’t sign up for. However, only 13% (12% NDUs, 15% PDUs, 13% CDUs; $p = 0.62$) said they would ignore the risks of a study if researchers paid them “a lot” to participate. Just fewer than 80% (78% overall) agreed that researchers should be able to offer “a lot” to get people to sign up for a study. PDUs were more likely than both CDUs and NDUs to think that researchers should be allowed to offer “a lot” of money to get participants to sign up for a study (86% PDU vs 75% CDU; $\chi^2 (1, n=473) = 7.1263, p = 0.0076$) (86% PDU vs 74% NDU; $\chi^2 (1, n=299) = 6.8386, p = 0.0089$).

PDUs and NDUs were more likely than CDUs to say that it was fair for researchers doing studies on high blood pressure, diabetes, and HIV to routinely exclude drug users from their samples (60%PDU vs 41%CDU; $\chi^2 (1, n=475) = 16.9885, p < 0.0001$) (61%NDU vs 41%CDU; $\chi^2 (1, n=452) = 16.3634, p < 0.0001$).

When asked about uncommon informed consent preferences, participants did not differ across drug use groups in their responses. About 45% of the sample said they would like researchers to read the whole informed consent out loud to them. The vast majority of the sample (96%) responded that they would like researchers to ask them questions to make sure they understood information about the study before they agree to be in the study and most (88%) wanted researchers to make sure they were not high on drugs before asking for consent. About 13% of participants wanted a friend with them during the time of consent and 15% wanted a family member. A little less

than a third (32%) of the sample said that they would like to have a stranger not connected with the research team to help them understand the study at the time of consent. Additionally, over two-thirds (69%) of the sample wanted to be reminded of what they agreed to do each time they came back for a study visit; this did not differ by drug use status. Roughly 22% of the sample said they would like to give their permission verbally instead of signing a consent form.

Table 3-1. Sample demographics by drug use status

	Total (N = 614) n (%)	Never drug users (N = 139) n (%)	Past drug users (N = 162) n (%)	Current drug users (N = 313) n (%)	<i>p</i>
Age μ (std):	43.4 (13.5)	43.6 (15.4)	46.6 (11.5)	41.7 (13.4)	0.0007 ^c
Female:	322 (52.4)	92 (66.2)	91 (56.2)	139 (44.4)	<0.0001 ^{b,c}
Race/Ethnicity (n=613):					
Black, Non-Hispanic	328 (53.5)	76 (54.7)	80 (49.4)	172 (55.1)	0.22
White, Non-Hispanic	232 (37.9)	47 (33.8)	72 (44.4)	113 (36.2)	
Other	53 (8.7)	16 (11.5)	10 (6.17)	27 (8.7)	
Marital status:					
Married	89 (14.5)	29 (20.9)	29 (17.9)	31 (9.9)	0.0002 ^{b,c}
Widowed/Separated/Divorced	222 (36.2)	44 (31.7)	72 (44.4)	106 (33.9)	
Never married	303 (49.3)	66 (47.5)	61 (37.7)	176 (56.2)	
Highest level of education:					
Less than high school	113 (18.4)	15 (10.8)	29 (17.9)	69 (22.0)	<0.0001 ^{a,b}
High school diploma/GED	368 (59.9)	71 (51.1)	97 (59.8)	200 (63.9)	
College degree	133 (21.7)	53 (38.1)	36 (22.2)	44 (14.1)	
Any employment in past 12 months:	304 (50.8)	66 (47.5)	79 (48.8)	159 (50.8)	0.79
Any medical insurance:	320 (52.1)	87 (62.6)	89 (54.9)	144 (46.0)	0.0034 ^b
Self – perceived health:					
Excellent/Good	322 (52.4)	89 (64.0)	80 (49.4)	153 (48.9)	0.0074 ^{a,b}
Fair/Poor	292 (47.6)	50 (36.0)	82 (50.6)	160 (51.1)	
Smoked cigarettes in past 12 months:	340 (55.4)	30 (21.6)	87 (53.7)	223 (71.3)	<0.0001 ^{a,b,c}
Drank alcohol in past 12 months:	445 (72.5)	68 (48.9)	107 (66.1)	270 (86.3)	<0.0001 ^{a,b,c}

a Never versus past users significantly different at the $\alpha < 0.05$ level.

b Never versus current users significantly different at the $\alpha < 0.05$ level.

c Past versus current users significantly different at the $\alpha < 0.05$ level.

Table 3-2. Research experience and interest by drug use status

	Total (N = 614) n (%) Yes	Never drug users (N = 139) n (%) Yes	Past drug users (N = 162) n (%) Yes	Current drug users (N = 313) n (%) Yes	<i>p</i>
Has ever been in health research study (n=610)	138 (22.6)	38 (27.7)	43 (26.5)	57 (18.3)	0.0340 ^{b,c}
Definitely interested in participating in research study	448 (73.0)	95 (68.4)	112 (69.1)	241 (77.0)	0.07
<i>Would volunteer for a health research study...</i>					
That only asked questions about your health	588 (95.8)	133 (95.7)	154 (95.1)	301 (96.2)	0.85
If researchers wanted to see your medical records	558 (90.9)	118 (84.9)	148 (91.4)	292 (93.3)	0.0229 ^b
If you had to give a blood sample	557 (90.7)	118 (84.9)	148 (91.4)	291 (93.0)	0.0314 ^b
If you were asked to give a sample for genetic studies	557 (90.7)	119 (85.6)	152 (93.8)	286 (91.4)	0.0499 ^a
If you might have to take medicine (n=611)	421 (68.9)	86 (61.9)	111 (68.9)	224 (72.0)	0.10
If you were asked to stay overnight in a hospital or clinic	500 (83.7)	101 (72.7)	137 (84.6)	262 (83.7)	0.0136 ^{a,b}
If you might have to use medical equipment (n=613)	542 (91.0)	117 (84.2)	141 (87.0)	284 (91.0)	0.09
If you weren't paid	460 (74.9)	97 (69.8)	129 (79.6)	234 (74.8)	0.14

a Never versus past users significantly different at the $\alpha < 0.05$ level.

b Never versus current users significantly different at the $\alpha < 0.05$ level.

c Past versus current users significantly different at the $\alpha < 0.05$ level.

Table 3-3. Perceptions of remuneration and exclusion by drug use status

	Total (N = 614)	Never drug users (N = 139)	Past drug users (N = 162)	Current drug users (N = 313)	<i>p</i>
	n (%) Yes	n (%) Yes	n (%) Yes	n (%) Yes	
<i>Perceptions of fair research payment</i>					
Research participants should be paid for their time	555 (90.4)	120 (86.3)	147 (90.7)	288 (92.0)	0.18
It is fair that some researchers are not allowed to pay drug users cash	478 (77.9)	117 (84.2)	135 (83.3)	226 (72.2)	0.0025 ^{b,c}
Fair compensation for a 1.5h study with an interview and a blood test					
\$0-20 n (%)	220 (35.9)	56 (40.6)	60 (37.0)	104 (33.2)	
\$21-30 n (%)	148 (24.1)	31 (22.5)	38 (23.5)	79 (25.2)	
\$31-50 n (%)	145 (23.7)	26 (18.8)	42 (25.9)	77 (24.6)	
\$51+ n (%)	100 (16.3)	25 (18.1)	22 (13.6)	53 (16.9)	0.56
If offered a gift card for fair amount instead of cash, I would still participate (n=605)	590 (97.8)	131 (97.0)	155 (97.5)	304 (97.8)	0.91
<i>Perceptions of coercive remuneration</i>					
“A lot” of money for a 1.5h study with an interview and a blood test					
\$0-50 n (%)	199 (32.5)	55 (39.9)	48 (29.6)	96 (30.7)	
\$51-100 n (%)	210 (34.3)	43 (31.2)	56 (34.6)	111 (35.5)	
\$101-200 n (%)	82 (13.4)	15 (10.9)	28 (17.3)	39(12.5)	
\$201+ n (%)	122 (19.9)	25 (18.1)	30 (18.5)	67 (21.5)	0.34
If offered a gift card for “a lot” instead of cash, I would still participate (n=611)	594 (97.2)	134 (97.1)	157 (96.9)	303 (97.4)	0.95
“A lot” of money would make you sign up for a study you normally wouldn’t sign up for (n=610)	289 (47.4)	63 (46.0)	87 (53.7)	139 (44.7)	0.17
You would ignore the risks of a study if researchers paid you “a lot” to participate (n=611)	82 (13.4)	16 (11.6)	25 (15.4)	41 (13.2)	0.62
Researchers should be allowed to offer “a lot” to get people to sign up for a study (n=610)	474 (77.7)	101 (73.7)	139 (85.8)	234 (75.2)	0.0107 ^{a,c}
<i>Perceptions of exclusion</i>					
Researchers doing studies on high blood pressure, diabetes and HIV often exclude people who are drug users. This is fair.	310 (50.5)	85 (61.2)	98 (60.5)	127 (40.6)	<0.0001 ^{b,c}

a Never versus past users significantly different at the $\alpha < 0.05$ level.

b Never versus current users significantly different at the $\alpha < 0.05$ level.

c Past versus current users significantly different at the $\alpha < 0.05$ level.

Table 3-4. Informed consent preferences by drug use status

	Total (N = 614) n (%) Yes	Never drug users (N = 139) n (%) Yes	Past drug users (N = 162) n (%) Yes	Current drug users (N = 313) n (%) Yes	<i>p</i>
You want researchers to read the whole informed consent form out loud to you	275 (44.8)	63 (45.3)	71 (43.8)	141 (45.1)	0.96
You want researchers to ask you questions to make sure you understood information about the study before you agreed to be in the study	590 (96.1)	33 (95.7)	155 (95.7)	302 (96.5)	0.88
You want researchers to make sure you were not high on drugs before asking you for your consent	541 (88.1)	126 (90.7)	146 (90.1)	269 (85.9)	0.24
You want a friend to be with you when researchers asked for your consent	83 (13.1)	20 (14.4)	22 (13.6)	41 (13.1)	0.93
You want a family member to be with you when researchers asked for your consent	92 (15.0)	23 (16.6)	25 (15.4)	44 (14.1)	0.78
You want a stranger who is not part of the research team, but who is trained to help you understand the study to be with you when researchers asked for your consent	197 (32.1)	46 (33.1)	46 (28.4)	105 (33.6)	0.50
You want researchers to remind you of what you agreed to do each time you came back	421 (68.6)	97 (69.8)	108 (66.7)	216 (69.0)	0.82
You would rather give your permission for a study verbally, without signing the consent form (n=613)	137 (22.4)	27 (19.4)	36 (22.4)	74 (23.6)	0.60

a Never versus past users significantly different at the $\alpha < 0.05$ level.

b Never versus current users significantly different at the $\alpha < 0.05$ level.

c Past versus current users significantly different at the $\alpha < 0.05$ level.

CHAPTER 4 DISCUSSION

Current Drug Users (CDUs) are just as willing as Past Drug Users (PDUs) to participate in health research and are more willing than Never Drug Users (NDUs) to participate in certain health research scenarios. Results show that CDUs were more likely than NDUs to volunteer for three types of studies: ones that required a blood draw, an overnight stay in a hospital or clinic, and giving a researcher access to medical records. Despite this increased interest and willingness to participate, CDUs were less likely to have participated in past research. This may be due in part to excessive and unethical exclusionary criteria or to researchers' reluctance to deal with drug using populations (Okuda et al., 2010; Blanco et al., 2008; Humphreys et al., 2008).

Other barriers to enrollment of drug users include higher attrition rates and fears that coercive remuneration or cash remuneration may lead to new drug use (Festinger et al., 2005). Research has shown the use of larger amounts of remuneration (particularly cash) is ideal for recruitment and retention of drug users and that participants of all types prefer cash to other modes of remuneration (Cottler et al., 1995; Deren et al., 1995; Festinger et al., 2005). However, in our findings among African American marijuana users (Webb et al., 2015), and in this study among all races and all drug users, we have found no differences by drug use status on what participants considered a fair amount of remuneration for a study lasting 1.5 hours that included an interview and a blood test. This signifies that drug users, past and current, do not need to be offered high amounts of remuneration to be enrolled and retained in health research. In addition, 98% of CDUs in this study said they were just as willing to participate in a study when they are offered a gift card as when they are offered cash,

showing that perhaps they are now used to this. Although almost all (90% overall) participants in this study agreed that study participants should be paid for their time, 75% of participants reported being willing to volunteer for a health study if they were not paid. Groups did not vary by their willingness to volunteer for a study if unpaid. Thus, despite asking multiple questions about remuneration amounts and form, we found no difference between people based on their drug use.

A little less than half of participants (47%) did say that being offered “a lot” would make them sign up for a study that they normally wouldn’t sign up for. In addition, most participants (78%) agreed that researchers should be allowed to offer “a lot” of money to get people to sign up. However, only 13% of participants said they would ignore the risks of a study if they were paid “a lot” to participate. Importantly, CDUs did not respond differently to statements of coercion than NDUs or PDUs. The majority of CDUs (87%) said they would not ignore the risks of a study if researchers paid them “a lot” to participate; this implies that drug users would not be more vulnerable to coercive remuneration than never-drug users or past drug users.

Unsurprisingly, CDUs were more likely than PDUs and NDUs to think it was not fair that some researchers are not allowed to pay drug users cash for their participation in research. However, still more than 70% of CDUs said they thought this practice was fair. Potentially even drug users believe the stereotype that their peers will spend cash remuneration on drugs.

Unexpectedly, PDUs agreed more with NDUs than CDUs on the routine exclusion of drug users from studies on high blood pressure, diabetes, and HIV. This possible negative attitude toward drug use may reflect the same type of adverse attitude

found among recovered alcohol dependents towards alcohol use. In addition, the amount of participants who believed it was fair to routinely exclude drug users from studies may show that the community needs to be better educated on medically and ethically appropriate exclusions.

Importantly, there were no differences between CDUs, PDUs, and NDUs on matters of informed consent preferences. Potential participants can be treated the same during the informed consent process. A vast majority of the sample wanted researchers to ask them questions to make sure they understood the study before they signed consent (96%) and also wanted researchers to make sure they were not high before asking for their consent (88%). This may signify that most participants, regardless of drug use status, believe it is the responsibility of the researcher to make sure that potential participants completely understand the study and are able to sign consent. Interestingly, nearly half (45%) of participants indicated that they would want researchers to read the whole informed consent form out loud to them. This may partially be because the informed consent document for our study was fairly short. Perhaps these participants would no longer agree with this statement if they knew consent documents could be up to 30 pages long.

These findings should be interpreted with the following limitations in mind. The data on drug use was self-reported, so there may be some misclassification if people felt uncomfortable sharing their drug use status with the interviewer. In order to limit this, we fully explained the Certificates of Confidentiality covering HealthStreet and the Navigation Study and sensitive drug use questions were asked at the middle of the interview, after interviewers had developed a rapport with participants. In addition,

many of the questions used in this analysis required participants to imagine themselves in hypothetical situations and some participants may have struggled to do this. However, it is unlikely that this introduced any differential bias. Also, the three groups differed on many demographics in addition to drug use. However, the high rates of willingness to participate and volunteer for research among all drug use groups make demographic differences less likely to bias findings. In addition, the majority of the drug users used marijuana only. Perhaps a different group of drug users would bring about different results. This and the fact that those comprising our sample come from a one county area in North Central Florida could mean that our findings are not generalizable to the US as a whole.

This study adds to the literature exploring research perceptions and interests among a drug using population. It can serve as foundational to future studies that help us better understand how to improve enrollment, retention, and the overall research study process for this population. This, in turn, will improve prevention and treatment outcomes.

Czarny and team (2010) set up study scenarios and looked for potential enrollment decision influencers. By combining Czarny's study methods (2010) and the methods employed in the current study, we could create detailed study scenarios and ask drug users what would influence their choice to participate, if they would participate, and how much money they would consider fair compensation for each study.

It is of great importance to include all populations in research to understand, for example, the effectiveness and effects of a medication on a specific population. Including drug users in research will help decrease health disparities not only among

the drug using population, but also among the entire population because findings will be generalizable to the entire community rather than to the select few who are chosen for clinical trials.

With the movement to legalize medical and recreational use of marijuana, Principle Investigators (PIs) and Coordinators will need to make inclusion decisions about those who have a history of marijuana and other drug use. This study can help reassure PIs and Coordinators that drug users are able to make appropriate enrollment decisions. Drug users do not want more money than non-users for a study that lasts 1.5 hours long and contains an interview and a blood test, and they are very willing to accept gift cards as compensation instead of cash. Drug users are interested in research and are willing to participate in all types of studies, even if they are not paid. Perhaps most importantly, drug users are not more likely to ignore risks of a study if “a lot” of money is offered to them.

This study was part of a larger NIDA-funded effort that aimed to deepen our already strong relationship with the local CTSA and to test an enhanced version on our community engagement program. One of our main goals in this study was to give members of a commonly excluded population a chance to have their voices heard in research for the first time. People who use drugs should be given the same chance to have their voice heard in research as people who do not. Treating all people as equals and not excluding them for non-medical reasons will diversify the research participant population. These methods are used regularly at HealthStreet and CTSA's around the US. We were successful in our goals and our findings highlight the importance of connecting with local CTSA's, using person-centered approaches, and finding each

population's attitudes and perceptions towards research to helping all populations become involved in research.

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BIOGRAPHICAL SKETCH

Amy Elliott received her MS in epidemiology from the University of Florida in May of 2016. During her graduate studies, she was a research assistant for Dr. Linda Cottler and Dr. Catherine Striley, working on several papers surrounding drug use and the research process. She had the privilege to work at HealthStreet, a community engagement program that works to connect underrepresented populations with research and health and social services. Amy received double BS degrees in health sciences and psychology from the Burnett Honors College at the University of Central Florida in 2013. While at UCF, she wrote an undergraduate thesis about social anxiety, self-injury, and high academic achievement. Her current research interests include drug use comorbidities, nosology, research perceptions, and anxiety disorders.