AIDS and Behavior (2018) 22:2258–2266
https://doi.org/10.1007/s10461-018-2114-5

ORIGINAL PAPER

# Participation in HIV Behavioral Research: Unanticipated Benefits and Burdens

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Published online: 30 April 2018


**Abstract**
HIV behavioral research has provided an invaluable knowledge base for effective approaches to behavioral challenges along the HIV care cascade. Little attention has been paid to tracking unanticipated effects of research participation, whether negative or positive. We used qualitative methods to elicit impressions of unanticipated effects of participation in behavioral research. An instrument was developed and piloted to assess positive (emotional gains, practical gains, HIV prevention knowledge and skills gains) and negative (emotional stress, discomfort with research) unanticipated effects. Participants (N = 25) from five projects, including men who have sex with men, adults who use substances, and youth, reported multiple positive unanticipated effects (sexual and drug risk reduction, goal setting, improvements in self-esteem and mood, relationship gains, health care behavior gains, knowledge and introspection gains) and rare unanticipated negative effects. Developing a systematic tool of unanticipated positive and negative effects of participation in behavioral research is a crucial next step.

**Keywords** Beneficial effects · HIV/AIDS · Behavioral research · Unanticipated effects · Adverse effects

**Resumen**
La investigación sobre comportamientos relativos al VIH ha proporcionado una base de conocimientos invalorables para lidiar efectivamente con los desafíos por conductas a lo largo de la cascada de atención por el VIH. Poca atención ha sido prestada en documentar los efectos imprevistos de la participación en investigación, ya sean negativos o positivos. Utilizamos métodos cualitativos para obtener impresiones de los efectos imprevistos de la participación en la investigación conductual. Se desarrolló y se aplicó un instrumento para evaluar los efectos positivos (ganancias emocionales, ganancias prácticas, conocimientos y ganancias de la prevención del VIH) y negativos (estrés emocional, incomodidad con la investigación). Los participantes (N = 25) de cinco proyectos, incluyendo hombres que tienen sexo con hombres, adultos que usan sustancias, y jóvenes, informaron múltiples efectos positivos no previamente anticipados (reducción del riesgo sexual y de drogas, establecimiento de metas, mejoras en la autoestima y el estado de ánimo, mejoras en relaciones personales, mejoras en buscar atención médica, ganancias de conocimiento e introspección) y raramente efectos negativos no anticipados. Desarrollar una herramienta sistemática para evaluar efectos positivos y negativos no anticipados de la participación en la investigación conductual es el paso crucial próximo.

**Palabras clave** Efectos beneficiosos · VIH/SIDA · Investigación conductual · Efectos no anticipados · Efectos adversos

## Introduction

HIV behavioral intervention research has provided crucial evidence of effective approaches to a variety of behavioral challenges along the HIV cascade. These include: HIV prevention [1–4]; participation in HIV testing and notification [5–9]; resilience and adaptation to diagnosis [10]; engagement in care and treatment [11, 12]; adherence to treatment

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[13, 14]; retention [15–18]; and coping with chronic illness [19]. For these, vigorous attention is paid to the scientific rigor with which interventions and assessment methods are developed and implemented. This often involves intensive formative inquiry with consumers, providers, and other stakeholders to assure the safety, feasibility, acceptability, and fit of these methods. However, there is far less attention paid to tracking unanticipated effects of research participation, whether negative or positive. As opposed to biological research, there is scant literature about the unanticipated effects of participating in behavioral research. In the U.S., federally funded biomedical and clinical trials research investigating medications, biologic agents, or devices on human subjects must use guidelines defined by the Food and Drug Administration (FDA) and the Common Rule documenting all "unanticipated problems" involving risks to participants to their Institutional Review Board (IRB), [20, 21]. Internationally, efforts are underway to report and catalog such effects in a uniform manner (e.g. Medical Dictionary for Regulatory Activities, World Health Organization Adverse Reaction Terminology, etc.) [22, 23].

In fact, in behavioral research in general, there is a gap in understanding the psychological and social risks of research participation [24, 25]. Reporting of adverse events in psychological treatments, if present, is often limited to criteria from biomedical research that may not be relevant [26]. A recent review of randomized clinical trials (RCT) of psychological interventions for patients with mental and behavioral disorders published during 2010 (N = 132) identified 28 trials (21%) that reported monitoring of harm to patients, and only 4 (3%) provided a description of adverse events as well as the methods used for collecting these data [27]. Recently there have been a few publications describing the development of principles for categorizing and measuring adverse events and unanticipated problems in behavioral or psychological intervention research within family focused substance abuse treatment [28], psychotherapy [29] and internet intervention trials [30]. A survey of clinicians' perspectives and experiences of possible negative effects of psychological treatments found that clinicians recognize that negative effects exist, but many were unfamiliar with methods and criteria for identifying and preventing deterioration and adverse events [31].

In one of the few publications examining the occurrence of serious adverse events (SAEs) in psychotherapy, psychosocial and behavioral intervention trials, Petry et al. [32] reported occurrences of SAEs in multicenter psychosocial trials (N = 1687) of the National Institute on Drug Abuse Clinical Trials Network. SAEs included any event that was life-threatening or harmful and could have resulted in hospitalization, persistent disability, or death. Incidence rates were compared across experimental and treatment-as-usual conditions to ascertain if interventions increased medical, psychiatric, or substance use SAEs; none of the 260 SAEs recorded during the 27,198 person-weeks of follow-up were judged by the Data Safety Monitoring Board to be study related, and there were no significant differences between experimental and control conditions in SAE incidence rates. However, unanticipated effects of participation in HIV behavioral research go beyond the SAEs examined.

Recognizing that participation in HIV behavioral research may be a stimulus for both adverse and beneficial unintended effects, we sought to identify these. The aim of this study was to elicit preliminary qualitative data about the unanticipated effects of participation in HIV behavioral research by gathering impressions from a diverse sample. Standard regulatory approaches are concerned with unanticipated problems, which are not identified in study consent or protocol documents. We took a broader view of unanticipated effects than that of the regulatory literature. Whereas previous literature focused primarily on physical and medical side effects of research participation, the current study explores both negative and positive unanticipated psychological and social effects of participating in behavioral research. This study was intended to serve as an exploratory platform—from which to develop a preliminary nomenclature for describing unanticipated effects of participation in HIV behavioral research. Results obtained could provide the basis for constructing a brief tool that could be used on a wider scale to assess and document unanticipated effects of participation in HIV behavioral research, and potential procedures required to address them. The study was approved by the New York State Psychiatric Institute IRB.

## Methods

### Sample

Twenty-five participants completing HIV behavioral studies were interviewed about their research experiences and perceptions of effects of participation in research. Sociodemographic characteristics are presented as aggregate data for confidentiality purposes. About half (52%) were male. Age ranged from 18 to 45 years old. Participants were recruited from five ongoing studies in the HIV Center for Clinical and Behavioral Studies of the New York State Psychiatric Institute. All participants had completed final interviews within the prior 12 months. Studies were selected to include a range of HIV Center projects (e.g. assessment only versus intervention research) and participants from a range of demographic backgrounds, risk levels, or research settings. These included studies on: (1) the role of masculinity-related factors on sexual behavior (N = 2); (2) substance use and HIV sexual risk behavior among high risk and HIV positive men who have sex with men (MSM) (N = 8); (3) HIV prevention

intervention for adolescents (N = 5); (4) HIV/STD prevention intervention for high HIV risk women in substance use outpatient treatment programs (N = 8); and (5) HIV/STD prevention intervention for high HIV risk men in substance use outpatient treatment programs (N = 2).

Participants were referred by the host study's Principal Investigator and fulfilled the following eligibility criteria: (1) were between the ages of 18–65; (2) English speaking; (3) able to give informed consent and capable of understanding the study information sheet; and 4) recently completed their participation in an HIV Center research project (less than 12 months). This prevented our study from interfering with individuals' participation in the host study. Participants received $30 dollars, in cash or gift cards, at the end of the interview.

### Instrument

Interviewers used a semi-structured individual qualitative interview to elicit participants' own perceptions of their research experiences, in their own words [33]. Instrument development was based on prior literature and information obtained from discussions among research teams (i.e., investigators, coordinators, interviewers, interventionists, outreach workers) from 11 projects. These were HIV assessment or intervention studies of diverse populations (inner city New York City [NYC] HIV+ and HIV− high risk adolescents, inner city NYC female substance users, inner city NYC Latino MSM, NYC MSM of various ethnicities, NYC HIV serodiscordant gay male couples, and Brazilian high HIV risk adults in psychiatric care) based at the HIV Center for Clinical and Behavioral Studies. Teams discussed their responses to one question about what unintended positive and negative effects their study participants experienced from being in their studies.

All interview questions started from a general, non-directive stance to give the participant the greatest possible freedom to answer, according to his/her own perceptions, and in his/her own words. After initial response was given to a question, follow-up probes were used to elicit clarification and additional responses. For each response, probes were used to elicit the participant's perception of these experiences as positive and/or negative.

There were five interview sections: (1) experience of research procedures (e.g. reaction to required disclosure of personal information, time commitment, compensation, interaction with researcher, unanticipated impact of intervention); (2) effects of research participation on key aspects of daily functioning and life experience (e.g. practical responsibilities, mood, self-esteem, interpersonal relationships, substance use, work, sexual behavior, services access and use); (3) concurrent life events and personal changes during the course project participation, attributed to study participation by the participant; (4) impressions of major features of research procedure, including informed consent, sense of preparedness, basic study activities (i.e. assessment only or assessment and intervention), confidentiality, risk/benefit of participation, and overall satisfaction with their research experience and whether or not they would recommend research to friends, and other topics; and (5) concurrent life changes that the participant may not perceive as study-related. At the start of the interview, questions were posed to ascertain the time frame of each participant's course in the host project using significant events (e.g. birthdays, holidays) to establish this time frame. Once established, all subsequent interview questions were anchored in this time frame. The instrument was pre-piloted with the first two participants in each of two host projects. Interviews were audio recorded and transcribed at a later time.

A systematic coding procedure was used to characterize the positive and negative effects of participation in HIV behavioral research, from the interview material. Our coding procedure was comprised of three major activities: [1] Development of the codebook and coder reliability: To develop the codebook, a team of four investigator-coders independently coded three transcribed interviews. The coding for these was collectively discussed, and consensus (i.e. at 100% level of agreement for all codes) was attained. The resulting codebook was used to code the study interviews. [2] Distinguishing unintended (versus intended) effects of research participation (for each study in which participants had taken part): The four coders checked the participant's description of research effects against the study outcomes listed in each study's IRB protocol. For each participant's interview, only reports of experiences that were not intended outcomes of the study in which he/she took part were determined to be unintended effects. For intervention trials, if the participant had been in an inactive control arm, his/her description of experiences that were anticipated study outcomes only for the active intervention arm were classified as unintended effects. [3] Ongoing coding: After the team of four investigator-coders had attained reliability, any given interview was double-coded by two investigator-coders. Using QSR International's NVivo 10 Software, coded interviews were entered into a database for analysis, following the codebook. As interviews were coded, the codebook was expanded on an as-needed basis, to capture novel responses. Previously coded transcripts were reviewed to code any of these responses.

## Results

Findings about the eight major domains identified through study participant interviews are presented below.

### Sexual Risk and Substance Use Behavior

For over a third of the participants, participating in HIV behavioral research was a trigger for positive change in risk behavior. No participant reported a negative response to questions examining their sexual risk or substance use behavior. Participants described being primed by questions to reflect on a range of topics related to risk and prevention. These included: risk behavior and its consequences; risk reduction and its effects; and personal values or goals, and their interplay with these behaviors. For example, one individual reflected: "I would sit there and be answering these questions about having, you know, protected or unprotected sex. And I kept thinking to myself, 'What am I doing to myself? I'm killing myself.' So yeah, I think the study did have an effect on my sexual behavior. Yes it did". These positive changes took various forms. Most commonly, participants reported increasing condom use, "I always try to use condoms because I know what I have. You know, so nobody else get it… I use a condom always now". This was often described as increasing "protection". Frequently, participants described reducing their risk behavior. This chiefly included reducing frequency of sexual risk behavior, "It made me cut back on things that I shouldn't be doing, like that I don't really—hanging out like that and having unprotected sex and stuff…It has lowered the amount of times I have–I have had sex..". Some emphasized reducing their combined use of drugs or alcohol with sex, "… it made me think about was that if I were to [not] continue some of those behaviors, that there would not be those connections. Like, if I decided that I was [not] going to be a drug addict, then I wouldn't continue having risky behavior while I was on drugs…maybe I don't have to be a practicing drug addict that much…The frequency and the intensity". Less often, participants discussed negotiating safer sex, "But now, I could say no to myself. And be like, 'Listen, I don't know you.' You know. 'I like you, but we should go check.' You know, 'You don't know if I have something either,' you know". Less often, participants described opting for abstinence:

> I didn't want to actually have sex with him. I mean, to have sex with him for me became a chore. Wow, that sounds awful. But it's the truth. Could I relate it to the study? I hadn't really thought about it. Did the study maybe indirectly have some effect on it? Perhaps. Perhaps. Or was it, you know, my own education of the risks? Maybe it was a combination of both.

Positive effects on substance use behavior were common. Participants described reducing frequency and/or quantity of their substance use, "Yeah, so… It just made me realize that… Like say I did it… Like say ten, fifteen times out of a month, it made me cut down to like maybe a couple a times a month. You know, it's getting better. It's not all the way clear, but, you know, it got—you know, it got down some". They also described initiating abstinence from substance use. As described below, these changes were often linked to initiating or increasing participation in substance use treatment.

### Goals and Enlightenment

Several participants expressed newfound insight into themselves or the world around them, changing their general outlook. For the purposes of this study, these assertions were coded as *Enlightenment* or *Gained a New Existential Perspective.* One participant reported a profound change as a result of participation in behavioral research, stating, "…doors were starting to open up, and I just started opening them doors and learning more. …I just started opening doors, where before I didn't open the doors, I would just, mainly just look at it. And if it didn't, it just, you know, I wouldn't open the door". Another interviewee asserted: "The research helped. It made me put things in more perspective, thinking about a lot of things in my life in general".

Even more prevalent was language related to changes in one's goals and aspirations for the better. Thirteen of the twenty-five interviewees expressed that they have become more focused in achieving their goals, developed new goals and/or improved their perceptions of the future as a result of participating in a behavioral research study. One participant remarked, "It just made me want to strive for better things in life and try to, you know, cut the drugs out and leave that alone for good and, you know, try to be a better person".

Questions asked in the research studies also made participants reflect on their own lives, behaviors, and how they are viewed by friends, family, and the world at large. One stated: "I started to look around and see how I was viewed by other people, and I have to change some behaviors that I did have". Another participant described: "Like my definition of a man, and my definition of masculinity, think about how people see me in that role, and like my job, and my sexuality, and how most people don't put those together, and things like that".

### Stigma

The primary foci of the studies in this research—on HIV or HIV risk, and/or problem substance use—prompted questions about stigma from participating in these studies. This is because living with HIV, being at higher risk for HIV, or having substance use problems are often triggers for stigma. Just participating in such studies, in the presence of others, could make a participant vulnerable to rumors of having HIV, engaging in higher risk behavior, and/or abusing substances. Despite the pervasiveness of such stigma, comments related to stigma were rare in the interviews. Only

two interviewees reported feeling marginalized as result of participating in a study, reporting that there was an assumption of negative behavior if they participate in studies such as these (e.g. risk reduction interventions). However, one reported that being in a study also lessened this stigma. The participant felt an affiliation with similar individuals, stating "… just that group alone put my mind at rest that I wasn't a monster…"

## Self-esteem and Mood

For many of the participants there was a positive effect on their self-esteem and mood from participating in the research. This often involved their increase in self-esteem due to self-examination, "At that time it made me look at myself, that I could do more for myself instead of staying in the situation I am in…It made me feel positive about the future, that I don't have to be alone for the rest of my life". Others reported an increase in self-esteem in relation to feeling similar to others "…I could… talk to another person that, um, may have been going through the same situation that I have.. it gives a good feedback. It's a good thing". Another participant added "I felt smarter. I walked away feeling good from the group every day, every time we went". Mood improvement was also mentioned by six participants as a result of research participation, "I feel good that I helped the research world".

On the other hand, a few participants also reported remorse or shame over their past behaviors, "Because sometimes you think about what you've done. I was…a prostitute prior… it makes you think about your past life and what you've done, and I should have used safer sex because I have herpes…it doesn't lower your self-esteem, but it makes you think".

## Relationships

The majority of participants reported at least some effect of the research on their personal relationships, whether it be with family, friends, or others with whom they may be sexually involved. For many participants, there was increased harm reduction talk in relation to others: "You know, when I learned about things like I could hurt people by committing these mistakes…getting high…having unsafe sex…I said 'Why am I going to go this way? Let me go another way.' Like I protect myself, the partner I'm with, my wife and… my kids". One participant reported an initial strain in her romantic relationship after increasing condom use to prevent HCV transmission. However, the participant noted that ultimately this was a "positive thing".

Other participants reported sharing the information that they had learned with others and increasing the dialogue between family members. For example, one stated: "Like a lot of knowledge…I bring a lot to my son. He's 23 now…let me—you help him, you know stay safe".

## Health Care Behavior

For a third of the sample, taking part in HIV behavioral research was an impetus to contemplating, initiating, or increasing participation in appropriate health care services. One individual reflected: "You start to think, so you're not being so reckless, and you're not, you know, just going out and getting high, So what it is—you know—you start to take a little more care of yourself". For two participants in need, study discussion of the link between sexual risk behavior and substance use prompted enrollment in drug or alcohol treatment programs. One stated: "…I started participating in day treatments and other harm reduction, um, stuff. So I learned… about harm reduction and afterwards, it started making more sense to me". Another reported increasing attendance in his program. Four participants sought HIV testing. One reported: "Yes, I actually got tested. Here at the clinic. I got tested when I first came, and maybe about like two months ago I took another test just to make sure. And it came negative". Another two newly resolved to seek HIV and STI testing. Three participants sought appointments for medical examinations they had previously delayed—for hepatitis-related issues, gynecologic and breast examination, and general primary care (i.e. one each). One participant increased adherence to psychotropic medication. No participant reported negative effects on health care behavior from study participation. No participant reported negative or positive effects on participation in non-medical (e.g. social) services.

## Knowledge

A majority of the sample had positive responses when asked whether or not they had gained knowledge during their participation in research. There were no negative responses. Most knowledge gain reports were related to topics covered during the interventions. For example, one stated: "So, it's important…that class taught me how to teach my children to do things the right way," and how they can affect those around them. Another stated: "Well, reality's like I felt something hot in my heart…Like, look at this, I could just get my wife sick…she could have died…" Participants also remarked that knowledge of available resources allowed them to feel supported. One reported: "There are people who do care and knowing that there are resources or a place to go to, you know, in case you are ever in need of anything… they had other resources that was connected to the study and so it let you know that you weren't alone in all of this, and so it was cool".

### Research Features

More than half of participants responded that overall the research itself was a positive experience. The rest reported no effect. When asked if they would refer a friend to research, twenty-three participants said "Yes" and two said "No". These two participants cited discomfort with questions, confidentiality concerns, and research burden as reasons for holding them back from referring friends.

## Discussion

Beyond intended outcomes, behavioral research can have a substantial effect on participants. Yet, the potential for positive—in addition to negative—effects has rarely been explored. This is in spite of abundant suggestion—from widespread findings of improvement in control or comparison conditions in psychological intervention trials—that participation in such research can have beneficial impact on participants [34]. In the present study, we identified relevant domains, and, within the context of HIV behavioral research, conducted exploratory work to address them. This study describes the use of a brief qualitative interview to elicit study participants' experiences of participation in HIV behavioral research. This interview had the advantage of eliciting participants' experiences in their own words. Several salient findings emerged from the participant interviews.

First: Mainly, questions about risk behavior seemed to have a constructive effect on behavior. The process of self-assessment appeared to help participants reflect on their behavior, consider its effects on their lives, and re-compose or re-affirm health-positive values and goals going forward. This is an effect described in the HIV behavioral research literature as assessment "reactivity" [35]. Similarly, the change potential of assessing and reporting behavior is a key element of cognitive behavioral interventions [36].

Second: Positive impact in one domain often appeared to transfer to other domains. For example, felt gains in committing to safer sex practices might prompt an individual to pursue a health care need, long avoided. This is an effect described in psychological intervention literature as "transfer" [37].

Third: In behavioral research, there is strong potential for so-called "non-specific" effects—from the intensive processes needed for engagement, and, in ongoing research, retention. One such effect is the Hawthorne Effect [38, 39]—a phenomenon in which individuals modify or improve behaviors simply in response to their awareness of being observed. Another such effect is the Placebo Effect—a phenomenon in which individuals in a trial may experience improvement in the absence of actual active intervention. Rather, the mere explanation of potential study benefits in the research consent process may trigger individuals' perceptions of gain from participation [40]. Further, being in a study may increase actual proximity to services. In the studies our participants took part in, enhanced attention and support, and, even, linkage to services needed, was a standard part of engagement and retention. Such studies, reviewed by IRBs and funding agencies for their attentiveness to participants, often go above and beyond the intensity of service feasible in the high volume inner-city clinics or facilities where our study participants usually received care. This is especially true when individuals are members of traditionally marginalized populations, as was the case with many of our participants. Altogether, these "non-specific" effects, including those that are attitudinal and those that directly increase access to services, are possible drivers of increased health care behavior in research participants.

Fourth: Social Desirability bias could have explained the fact that participants interviewed tended to describe virtually only positive effects about study participation [41–43]. However, we interviewed participants after they left the 'host' projects to maximize the prospects of their speaking freely and candidly. We assured them of the confidentiality of their responses, and of the lack of potential consequences of discussing negative effects. Yet, participants likely formed connections to the host project and staff. This may have made them reluctant to report negative effects of study participation.

The rarity of unanticipated negative effects was striking. We expected expressions of concern about possible intrusiveness of personal questions, use of explicit sexual questions, and their experience of being dealt with as a research subject. We were also alert to the prospect that discussion of risk behavior or substance use might awaken interest in risk behavior or stimulate cravings for substances—which participants did not report. We were also alert to the prospect that participants' involvement in this research could elicit concerns about negative reactions from sexual partners or relatives—which participants did not report either.

The current study explored unanticipated effects of research participation in a small sample of individuals from a group of HIV behavioral research studies from one research center in the U.S. As such, it is limited in scope. However, it has broader implications for behavioral intervention research being conducted on a far greater, in fact, global scale. These studies of efficacious behavioral and psychotherapeutic interventions are being enthusiastically conducted in low- and middle-income countries, especially where resources are scarce [44]. The lack of systems for tracking research effects is a significant gap in these trials, in need of improvement [24, 25]. A standardized assessment and reporting system of the effects of an investigational behavioral intervention, and/or the effects of participation in behavioral research would address this gap. It would be

important to extend the type of inquiry conducted in the current study to these settings.

Some of our findings may be artifacts of our study limitations. In particular, our sample was a very small volunteer sample. They were willing to participate in this research—beyond the study from which they were recruited. There may be social desirability effects. However, stipends for participation likely helped to attract a wider variety of individuals—beyond exceptionally motivated individuals. Qualitative assessment eliciting participants' own words likely helped to address this limitation. Future research should combine the use quantitative and qualitative assessments to explore unanticipated positive and negative effects of research participation and ensure that social desirability does not decrease reporting.

## Limitations

Although our findings are heartening, they are constrained by several study limitations. First: This was a small, single-assessment, exploratory study of volunteer participants. All had completed final interviews, within the past year, in research projects. Such study completers are more likely to have benefited from their research participation, and to have attained positive outcomes. This would have the potential to inflate the impression of positive research effects. Recruiting drop-outs, as well as completers, would have had greater potential to elicit a broader range of responses. Second: As a small, exploratory study, we did not have sufficient sample size, nor systematically varied sampling, to determine potential relationships between participant characteristics and report of research effects. Surely, this would be an extremely useful understanding to have obtained. Third: Based in self-report, our data were susceptible to social desirability effects. As described above, effort was made to minimize this; however, we cannot assume that we eliminated social desirability effects. Fourth: As a single-assessment study, in which we did not ask about length of experiences, we do not know about the duration of research effects described by participants. The ideal design for future research would be a large, prospective, longitudinal study, starting at participants' entry into research projects. Participants could be followed over time, and compared as they, respectively, become completers or drop-outs.

**Acknowledgements** Supported by: NIMH HIV Center for Clinical and Behavioral Studies Grant P30 MH43520 (PI: Robert Remien); NIDA Drug Abuse Clinical Trials Network Grant U10DA13035 (PIs: Edward Nunes, John Rotrosen); NIMH R01 MH65163 (PI: Milton L. Wainberg); and NIDA R01 DA026775 (PI: Milton L. Wainberg).

**Funding** This study was funded by NIMH (P30 MH43520 and R01 MH65163) and NIDA (U10DA13035 and R01 DA026775).

## Compliance with Ethical Standards

**Conflict of interest** Susan Tross declares that she has no conflict of interest. Veronica Pinho declares that she has no conflict of interest. Jennifer E. Lima declares that she has no conflict of interest. Megan Ghiroli declares that she has no conflict of interest. Katherine S. Elkington declares that she has no conflict of interest. David H. Strauss declares that he has no conflict of interest. Milton L. Wainberg declares that he has no conflict of interest.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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