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Running heading:

Challenges to Studying Illicit Drug Users

Title:

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Illicit drug use, research ethics, research methodology, vulnerable populations

Heading level 2:

Abstract

Purpose: Throughout the world, illicit drug use continues to pose a significant risk to public health. The opioid crisis in North America, the diversion of the prescription drug tramadol throughout Africa, and the increasing supply of methamphetamines in East and South Asia all contribute to increasing risks to individual and societal health. Furthermore, the violation of human rights in efforts to enforce prohibitionist values poses significant threats to many individuals worldwide. With these evolving situations, it is imperative that researchers direct their attention to the various populations of illicit drug users. However, the inclusion of illicit drug users, often considered a vulnerable population, as participants in research studies presents several increased risks that must be addressed in study protocols. Researchers are required to provide "additional safeguards" to all study protocols involving illicit drug users, but there is often substantial variability and inconsistency in how these safeguards are applied. Additional safeguards can be timely, costly, and unduly burdensome for researchers, ethical review boards, and research participants.

Approach: Through synthesis of the current literature, this article addresses the barriers to studying illicit drug users and the methods researchers can utilize to minimize risk. A case study is provided to illustrate the high level of scrutiny of study protocols involving the participation of illicit drug users and the effect of such scrutiny on recruitment of participants. The article concludes with a discussion of the effects of the current political climate on the recruitment of

illicit drug users in research.

Conclusions: Individuals who participate in criminal or illegal behaviors such as illicit drug use, prostitution, illegal entry into a country, and human trafficking are susceptible to multiple physical, mental, and social health risks, as well as criminal prosecution. The importance of research on the health of marginalized populations cannot be overstated. This work must continue, and at the same time, we must continue to protect these individuals to the best of our ability through diligent attention to sound research methods.

Clinical Relevance: The use of illicit drugs continues to pose a substantial threat to global health. Individuals who use illicit drugs are susceptible to multiple physical, mental, and social health risks, as well as criminal prosecution. It is imperative that researchers study these vulnerable populations in order to develop interventions to minimize individual and societal harm. There are several barriers to the study of illicit drug users that must be addressed through rigorous methodology and the addition of safeguards.

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Body of article:

An estimated 275 million individuals worldwide, or 5.6% of the global population 16 to 54 years of age, used an illicit drug at least once in 2016 (United Nations Office on Drugs and Crime [UNODC], 2018). An estimated 450,000 individuals died as a result of their drug use; 167,750 directly from drug use disorders (mostly overdose), and the remainder from drug use-related illnesses such as hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Cannabis continues to be the most widely used illicit substance, with an estimated 192 million users worldwide, while opioids continue to cause the most harm, accounting for 76% of drug use disorder-related deaths. The opioid crisis in North America has reached epidemic proportions, and has rightfully received international attention. However, other regions around the world have also been affected by supply-driven expansion of drug markets. In parts of Africa

and Asia, illicit use of the opioid tramadol is increasing at alarming rates. In East and Southeast Asia, the increased trafficking of methamphetamines poses a significant threat to the health and security of the population in that region. This growing public health problem in underdeveloped countries is under-researched and has gone largely unnoticed. People who inject drugs (PWIDs), an estimated 15.6 million individuals worldwide, continue to sustain the greatest health risks; more than half have been exposed to HCV and one in six lives with HIV (Degenhardt et al., 2017).

Of significant concern to public health providers is the lack of services for those experiencing substance use disorders (SUDs). Only one in six individuals with SUDs received any treatment for those disorders in 2016 (UNODC, 2018). Furthermore, access to evidence-based harm reduction strategies such as opioid substitution therapy (OST) varies by geographic location, ranging from 90% of PWIDs in the United Kingdom having access to OST, to none in the Russian Federation, where OST is not allowed (Mathers et al., 2010). These disparities create significant barriers to treatment. While OST is endorsed by the Joint United Nations Program on HIV/AIDS, the UNODC, and the World Health Organization (2009), many developing countries question this therapy and instead continue to promote abstinence-only treatment goals, frequently violating human rights (Jurgens, Csete, Amon, Baral, & Beyrer, 2010).

Finally, while international treaties such as the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971, and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 provided guidance for the scheduling and prohibition of psychotropic substances, enforcement of these policies varies greatly among nation states. For example, Uruguay, Canada, and 10 U.S. states have legalized the possession and retail sale of cannabis; Spain, Mexico, and the Netherlands have allowed for personal possession of cannabis; but in Malaysia, cannabis possession of over 7 ounces is considered trafficking and if convicted is punishable by the death penalty (U.S. Department of State, 2010).

The substantial variability among drug use patterns and drug enforcement laws across the world creates significant hurdles for

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researchers attempting to study the vulnerable population of drug users. However, given the substantial contribution of substance misuse to individual and societal harm, it is essential that researchers continue to study the multiple aspects of substance use and misuse. Substance use research raises a unique set of ethical challenges that can interfere with the efforts of researchers to study illicit drug users. It is important for researchers to acknowledge these challenges and develop novel methods and designs to protect vulnerable populations participating in research and assure that this much needed research is being performed. Studying these populations helps researchers to understand the underlying causes of drug use behavior and develop interventions to minimize harm from illicit drug use. The inclusion of illicit drug users, often considered vulnerable participants, in research presents several increased risks that must be addressed in study protocols. These risks can prolong and intensify ethical review processes. This article discusses both the perceived and actual risks to illicit drug users participating in research, as well as the safeguards researchers can utilize to mitigate these risks. A case study is provided to illustrate the high level of scrutiny of study protocols that involve the participation of illicit drug users and its effect on recruitment.

Heading level 1:

Risks to Illicit Drug Users Participating in Research

Major ethical challenges exist for substance use research, and many of these challenges continue to be unresolved (UNODC, 2004). Significant issues exist in several areas, including the capacity to give consent; limits to confidentiality; protection from legal hazards; and researcher training and understanding of the political, social, and economic settings in which their work is conducted (UNODC, 2004).

Heading level 2:

Informed Consent and Its Limits

There are multiple ethical concerns in drug use research about the ability of individuals using illicit drugs to provide informed consent.

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Valid informed consent requires participant comprehension and voluntariness (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Researchers often question the ability of drug users to give informed consent because the nature of addiction is such that potential participants may be intoxicated or experiencing withdrawal during the informed consent process, which might impede their comprehension and decision making (Anderson & DuBois, 2007; College on Problems of Drug Dependence, 1995). However, these concerns may be overstated. Two studies examining the informed consent process of PWIDs being recruited into HIV vaccine trials showed that PWIDs adequately understood the consent process (Harrison, Vlahov, Jones, Charron, & Clements, 1995) and performed as well on tests of comprehension as other non-substance-using participants (MacQueen et al., 1999). There is currently no systematic research on the impact of acute intoxication during the process of obtaining informed consent (Aldridge & Charles, 2008). Many researchers in the area of addiction and substance use acknowledge that in some situations, addiction impairs capacity, but it does not fully eliminate it (Bell & Salmon, 2011; Carter & Hall, 2008). Furthermore, if the intended goal of the research study involves frequently intoxicated individuals, then it can be argued that recruitment of such participants is preferable for reasons of validity (UNODC, 2004). Substance use researchers must therefore consider several ethical questions, including whether intoxication is an absolute exclusion criterion; how to determine the extent of intoxication, and how reliable that determination is; how to handle participants who are intoxicated but lucid; how to determine the judgment of an intoxicated participant; and when proxy consent might be appropriate (UNODC, 2004).

Other ethical concerns related to informed consent in research on illicit drug use exist beyond the question of comprehension and capacity. Most research protocols include policies for situations that require mandated reporting, such as suicidality, homicidality, and child abuse and endangerment. However, potential research participants are not always informed about these policies. McCrady and Bux (1999) surveyed 91 researchers funded by the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse, and found that participants were informed about these policies in only half the studies.

Confusion and lack of consensus exist on the need to inform participants of the limits of confidentiality. In situations in which participants pose a high risk for harm to themselves or others, ethics review boards require researchers to inform participants of the limits of confidentiality in the consent form (Check, Wolf, Dame, & Beskow, 2014; McCrady & Bux, 1999; Sieber, 1994). However, disclosure of these safeguards may result in decreased quality of data, with participants withholding pertinent information or withdrawing from the study, therefore compromising the validity of findings.

Heading level 2:

Confidentiality and Protection From Legal Hazards

It is critical that researchers protect the privacy of study participants and the confidentiality of all sensitive information that they provide. Many types of illicit drug use or prescription drug misuse are illegal, as are many activities related to drug use, such as driving while intoxicated, selling illicit drugs or diverting prescription drugs, and violence and crime while using drugs or in an attempt to finance drug use. In most places in the world, study participants could face criminal charges if study data were linked to individuals by law enforcement. In the United States, a Certificate of Confidentiality (COC) can be obtained to assure confidentiality of study participants, as described below. However, in all other countries of the world in which a COC does not exist, the situation is much less clear (UNODC, 2004). Even when protective measures are taken to ensure participant confidentiality, in some countries researchers may be compelled by the courts to provide study information to law enforcement. The ability of a researcher to protect the anonymity of participants and confidentiality of the information is paramount for substance use research; however, the ability of the researcher to maintain confidentiality is often limited by the regulatory frameworks governing the research (Small, Maher, & Kerr, 2014). Unlike physician-patient and attorney-client relationships, the researcher-participant relationship is not privileged, and therefore is not provided the same protections for absolute confidentiality (Stone, 2002). In the absence of privilege, a participant might be reluctant to

participate or decline participation altogether. In those situations, the loss of research participation can result in a significant loss for society, particularly for the vulnerable population being studied.

Heading level 2:

Researchers' Understanding of Political, Social, and Economic Settings

The ethical challenges facing substance use researchers can be amplified in situations where researchers are exploring drug use across different cultures, particularly in developing countries where there is little tradition of conducting research, and ethical institutions and review processes are not well established (UNODC, 2004). Drug use research has primarily been developed in industrialized nations such as the United States and Great Britain, both of which have significant societal resources to devote to this research. Substance use research therefore developed from Western biomedical models, and ethical challenges will increase as the research extends beyond these models and settings. International collaboration can therefore help to resolve these issues, and will allow substance use researchers to view drug use through multiple lenses.

Heading level 2:

The Role of Ethics Review Boards

Research ethics boards (REBs) and institutional review boards (IRBs) were first developed in response to the ethical challenges of basic and clinical research. However, the predominance of the biomedical research model within review frameworks can make it difficult for REBs and IRBs to conceptualize the risks unique to social science research (Small et al., 2014). Their lack of familiarity with social sciences research can result in overemphasis on the biomedical approach to ethics review, while overlooking or failing to understand the complexities of community-based research (Malone, Yerger, McGruder, & Froelicher, 2006; Souleymanov et al., 2016).

Research focusing on controversial public health issues such as illicit drug use, human trafficking, and illegal arms trade requires the

collection of sensitive information from participants who may be engaged in unlawful activity. There is considerable agreement that research on these issues is of great prospective value to society, because it has the potential to decrease the individual and societal harms of illegal activity. However, REBs and IRBs frequently raise concerns that these populations, which could be considered vulnerable, are at increased risk for coercion in research and therefore require special protection (Office for Human Research Protections, 2010). The Common Rule, which guides IRBs in the United States, states:

Inset quote:

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. (U.S. Department of Health and Human Services, 2018, 46.111(b))

The vagueness of “additional safeguards” places a heavy burden on researchers and ethics review boards who may not know exactly how to accomplish the goal of protecting these research participants, minimizing institutional liability (Anderson & DuBois, 2007). It is therefore not surprising that studies submitted to REBs or IRBs for drug use research often undergo intense scrutiny (Bell & Salmon, 2011).

However, protectionist concerns are often overstated (Anderson & DuBois, 2007; Small et al., 2014). Well-intentioned attempts to protect participants may markedly hinder research and severely impede their recruitment and participation in important research. This results in researchers’ inability to obtain information that is actually of potential benefit to individual participants, their communities, and society as a whole (Anderson & DuBois, 2007; Bell & Salmon, 2011). Greater involvement of individuals from the affected community of drug users in the ethics review process can help to correct some of these issues (Bell & Salmon, 2011; Small et al., 2014). Often ethics board members have little understanding of the realities of drug users’ lives (Bell & Salmon, 2011), and therefore, representation from drug user

communities as advisory members in the ethics review process could improve understanding (Australian Injecting and Illicit Drug Users League, 2010).

Heading level 2:

Additional Safeguards to Protect Illicit Drug Users Participating in Research

Researchers can apply several additional safeguards to protect the confidentiality of illicit drug users participating in research, and the sensitive data they provide. In the United States, researchers can obtain a COC from the National Institutes of Health. A COC protects researchers and their institution from state and federal subpoena, thereby preventing researchers from involuntary disclosure of participants' identities. All illicit drug users are committing federal crimes and therefore are at risk for prosecution if their identities are disclosed. A COC provides additional assurance to individuals who participate in illegal behaviors that their confidentiality will be maintained. However, the full extent of protection that the COC offers has yet to be determined (Anderson & DuBois, 2007; Duval & Salmon, 2004). In today's political climate, in which historical precedents are continually challenged, it is unclear how far a COC's protections would extend. In theory, the COC protects the researchers' documents, servers, and email accounts from the legal process of discovery. It is important to note that a COC protects the research team from involuntary disclosure, but does not prohibit them from voluntary disclosure. Researchers are not prevented from voluntarily disclosing situations, such as child abuse or subjects' intent to harm themselves or others.

Researchers working with vulnerable populations have ethical and legal obligations to protect the identity of their participants as well as any sensitive information they uncover during their study. Historically, this information was preserved on paper and stored in a locked cabinet. When study-related documents were transmitted they were mailed using the postal service. But in today's high technological age, data may be collected on iPhones and iPads, transferred to PCs or MACs, and emailed or downloaded; thus, the data are at risk for interception or access by unauthorized persons (hacking). All researchers must be aware

of the heightened security needed to protect the identity of their subjects and the sensitive data they provide. In order to minimize risk of unauthorized access (hacks), researchers must take extra precautions to ensure the safe collection and transfer of sensitive data. Every step of the research process must be scrutinized to ensure that information cannot be discovered. The institution's information technology department can provide detailed assistance to researchers concerned about the handling of sensitive data. Many commonly used research applications and software packages lack the necessary safety parameters to ensure protection of sensitive data. For example, iPhones should not be used to record interviews, because third-party apps on an iPhone can be subpoenaed to obtain the audio files. SurveyMonkey®, a common research tool, should not be used to obtain information about illegal activity because the company could be subpoenaed to release the Internet protocol addresses of the individuals participating in the survey, which could then be used to identify participants. All data collected should be stored on a secure server, the "locked cabinet" of the Information Age. All audio files and transcriptions should be encrypted and sent via safe file transport protocol as part of a secure shell protocol. All these extra safeguards are valuable in their added ability to protect participant confidentiality. However, the process to secure these additional safeguards is often protracted, resulting in substantial consumption of the researchers' time and budget. Furthermore, access to advanced technology and software is limited to individuals in institutions in developed countries. Researchers conducting field research in developing countries may lack the resources necessary to protect sensitive information from legal discovery.

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Case Study

To illustrate the many challenges researchers and ethics review boards face when attempting to study individuals using illicit drugs, we present the following case study. The primary investigator (PI) in this case was a doctoral candidate exploring the use of medical cannabis for pediatric epilepsy. The study's research approach was a qualitative

description design, and the study protocol included the use of one-to-one interviews with parents administering medical cannabis to their child or dependent for the relief of seizures. Because cannabis remains a federally prohibited drug, participants in this study risked federal prosecution, even when using the drug in accordance with their state's laws. Participants in this study were distributing a Schedule 1 drug to a minor, and federal prosecution could result in loss of custody of the child and up to 10 years of incarceration. Therefore, risk of involvement in this study was not solely limited to individuals' participation in the study, but extended to other family members. The ability of the research team to protect the confidentiality of participants was critical, given the increased risk to participants and their families. Throughout the 7-month IRB review and approval process, the study's protocol was scrutinized and important modifications were required to ensure the confidentiality of the participants in the study.

First, the PI obtained a COC from the National Institute of Nursing Research. In this case, the COC would protect the study's researchers and institution from federal subpoena, should the U.S. Department of Justice seek to prosecute the individuals participating in the study or those distributing medical cannabis to them. The COC would protect the PI from involuntary disclosure; however, as stated prior, it would not protect the PI from voluntary disclosure. Because medical cannabis for the treatment of seizure activity remains illegal in 20 states, its distribution to a minor in those states would be considered child abuse. Therefore, if the PI inadvertently interviewed individuals giving their child cannabis in states where its use was not legal, the research team would be mandated by law to report those individuals for child abuse, based upon their state's definition of the crime. In an effort to minimize the risk of inadvertently identifying individuals unlawfully using cannabis, the research team consulted the institution's general counsel. The general counsel provided advice and guidance to the research team throughout the IRB application and review process. The additional feedback from the general counsel resulted in additional safeguards to protect the confidentiality of the participants. Following the recommendation of general counsel and the IRB, the research team highlighted these eligibility requirements multiple times in the

recruitment flyer and consent form. The limits to confidentiality associated with mandated reporting of child abuse were clearly detailed (in bold) in the consent form:

There are two instances in which confidentiality may be broken:

Numbered list:

1. If the primary investigator is subpoenaed by the Federal Government to release the identity of the participants.
2. If the primary investigator observes any child abuse or neglect during the interviews. If child abuse or neglect is observed the investigator is mandated to report that to child services within the individual state.

To ensure that potential participants correctly understood the laws in their states, an Internet link was provided in the recruitment flyer directing potential participants to a website that clearly identifies the law on medical cannabis use for each individual state. To volunteer to participate in the study, the participant was instructed to email the PI. The PI then responded with a question as to whether or not potential participants were using medical cannabis in accordance with their state laws. If the potential participants were not, they were directed to cease any further correspondence and their email address was deleted from the server. This extra screening measure was in place to avoid inadvertent discovery of participants using medical cannabis illegally for their child.

These extra safeguards decreased the risk of inadvertently identifying individuals using cannabis illegally, and there were no instances in which the PI observed child abuse. However, the low level of response to outreach about the study among online medical cannabis advocacy communities who were initially enthused about the study led the research team to posit that risks presented in the consent form may have deterred eligible participants from participating in the study. It is difficult to assess whether the presentation of risks in the consent form affected recruitment, or if the risks themselves deterred individuals from participation.

Recruitment for the study was affected by several factors. The most important factor was the changing federal policy on prosecution of legal

medical cannabis users. The study protocol was designed during the Barack Obama administration, but following a lengthy IRB process the protocol was not initiated until the Donald Trump administration. Changes in leadership in the U.S. Department of Justice (USDOJ) resulted in significant policy changes regarding the federal prosecution of medical cannabis users, which may have had a substantial impact on recruitment for this study. On January 4, 2018, Attorney General Jefferson Sessions rescinded previous USDOJ memos that specified federal protections for individuals using cannabis in accordance with state laws (Sessions, 2018). This action created significant ambiguity and uncertainty for many medical cannabis users. Many potential volunteers for this study declined to participate due to fear of federal prosecution. During snowball referrals, the PI was told by one participant that other potential volunteers would not participate in the study due to the actions of the Attorney General. The PI had anticipated a federal policy change with the appointment of Attorney General Sessions, and was aware that this policy change could significantly jeopardize recruitment efforts. The PI was eager to begin recruitment before any policy change was initiated; however, the protracted IRB review process resulted in the delay of recruitment of almost 7 months, which greatly affected the study.

Recruitment for this study was also greatly hampered by the changing approach in the USDOJ. Despite initial enthusiasm for the study from marijuana advocacy groups, recruitment resulted in only three interview participants. It is difficult to assess whether the presentation of risk in the consent form deterred participation, or whether federal policy changes at the USDOJ had a stronger impact on potential participants' willingness to participate. It is noted that at least one comment on the recruitment postings indicated suspicion that the PI was actually a federal agent. Even with the multiple additional safeguards in place, the investigator was unable to recruit an adequate number of participants, and therefore the study's research design had to be modified. The investigator concluded that despite enhanced IRB scrutiny and the addition of multiple safeguards, potential participants still did not trust the research process. How researchers will address the lack of trust in the current political climate remains an important question for all researchers studying illicit drug use and other criminal

activities.

Heading level 1:

Discussion

REBs and IRBs have been subjected to increasing criticism and scrutiny (Abbott & Grady, 2011; Burman et al., 2003; Phillips, 1996). Critics of the current REB and IRB review system describe it as outdated and ill-equipped to handle the needs of current day researchers (Abbott & Grady, 2011; Maschke, 2012). There continues to be substantial variability among REBs and IRBs (Abbott & Grady, 2011; Kimberly, Hoehn, Feudtner, Nelson, & Schreiner, 2006; Larson, DeBasio, Mundinger, & Shoemaker, 1995). Variability from one ethics review board to another can be problematic when differences in assessments of risk and application of regulations exist, which can threaten the scientific merit and contributions of a study by decreasing productivity of the research team and increasing costs without enhancing participant protection (Abbott & Grady, 2011). The full impact of REB and IRB review on the protection of human research participants is difficult to measure. However, the failure of REBs and IRBs to protect human subjects can have serious and significant consequences to human research participants as well as research institutions and the researchers (*Gelsinger v. Trustees of the University of Pennsylvania*, 2000). REBs and IRBs are often charged with the difficult challenge of ensuring participant protection through meticulous review of study protocols, while maintaining efficiency to keep up with the pace of 20th century research.

The addition of safeguards to the standards of protection of human subjects, while beneficial to the confidentiality of participants, can be timely, costly, and burdensome to the research team. Overly burdensome study protocols can undermine the ability of investigators to acquire knowledge that is sorely needed to address health-related issues and social determinants of health outcomes, as well as the development of informed health policy. Advanced software designed to protect sensitive data often has a higher cost than conventional software and is limited to those with access in well-established research institutions in developed nations. Applications for the COC and ethics approval can be prolonged

due to the need to address the increased risk to participants. This delay can prevent the collection of time-sensitive data and can hinder efforts to examine current issues. The many extra steps needed to ensure that data collection is secure can be onerous for both participants and the research team.

Despite these safeguards, lack of trust, especially within the current political climate, can still deter participation in research. Trust is an important factor in the willingness of individuals to participate in research, particularly minority populations (Corbie-Smith, Thomas, & George, 2002; Millon-Underwood, Sanders, & Davis, 1993; Oransky, Fisher, Mahadevan, & Singer, 2009; Sengupta et al., 2000). Illicit drug users have expressed fear that participation in research could result in arrest, and that fear of getting caught or "busted" was perceived as a significant barrier to recruitment (Oransky et al., 2009). Researchers studying illicit drug users will have to take extra steps to secure trust with potential participants. Potential participants must be provided complete and honest information about the study, and about specifics regarding the extent and limits of confidentiality (Oransky et al., 2009).

Heading level 1:

Conclusions

The value and importance of information gained through the study of vulnerable populations outweighs the burden on research teams and ethics review boards. Individuals who participate in criminal or illegal behaviors such as illicit drug use, prostitution, illegal entry into a country, and human trafficking are susceptible to multiple physical, mental, and social health risks, as well as criminal prosecution, and we need to know how best to address these problems. Nursing research has a proud history of studying vulnerable populations. Those studies provide insight into the experiences of the individuals who live in the obscure corners of our society. The importance of research on the health of marginalized populations cannot be overstated. This work must continue, and at the same time, we must continue to protect these individuals to the best of our ability through diligent attention to sound research

methods.

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Clinical Resources

- National Institute on Drug Abuse. Addiction science.
<https://www.drugabuse.gov/related-topics/addiction-science>
- National Institute on Drug Abuse. Drugs, brains, and behavior: The science of addiction. <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface>
- National Institutes of Health, Office of Extramural Research. Certificates of confidentiality.
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Heading level 2:

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