Ethical issues in the conduct of longitudinal studies of addiction treatment

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Abstract

Many complex ethical issues arise in the day-to-day conduct of longitudinal studies of addiction treatment. These issues are rooted, in part, in the sustained and potentially ambiguous relationship between research staff and study participants, the frequently changing clinical and legal status of study participants, the assertive methods required to generate high follow-up rates, and the numerous systems of care and control in which participants are involved. To identify common ethical issues that arise in such studies, the authors conducted individual and group interviews with seasoned members (case trackers, field trackers, interviewers, and supervisors) of the research team. The ethical dilemmas identified through these interviews fell into seven broad arenas: (1) informed consent for research participation, (2) confidentiality and information disclosure, (3) relationship boundaries between study participants and research staff, (4) duty to warn/report responsibilities, (5) questions of autonomy and privacy, (6) issues related to compensation for research participation, and (7) data integrity. Case studies that illustrate common ethical dilemmas within each of these seven areas are presented and discussed. Ethical dilemmas in the study of addiction treatment can be effectively managed via ethically informed research protocols, staff training in ethical decision-making, monitoring and supervision, and collective debriefing of critical events. © 2005 Elsevier Inc.

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1. Introduction

Since its founding in 1986, the Lighthouse Institute, the research division of Chestnut Health Systems, has conducted treatment outcome studies for private, state, and federal agencies, including the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, the Center for Substance Abuse Treatment, and the Center for Substance Abuse Prevention. As our experience has grown in achieving high follow-up rates in longitudinal studies (Scott, 2004), so has our awareness of the special ethical issues that arise in the conduct of such studies.

There are several factors that contribute to the ethical complexities inherent in longitudinal studies of addiction treatment, including

- high percentage of persons who enter addiction treatment via external coercion
- prolonged duration and potential ambiguity regarding the nature of the relationships between research staff and study participants
- subcultures within which those with severe addiction problems are often embedded
- frequently changing clinical and legal status of study participants
- intensity of methods required to achieve and maintain high follow-up rates
- number and complexity of systems required to gain access to study participants.
The ethical issues that arise in longitudinal studies of addiction treatment are further complicated when the research participants present with heightened vulnerability, e.g., children and adolescents, pregnant women, persons with HIV/AIDS, prisoners, homeless persons, persons with co-occurring mental illness, and the indigent (Brody & Waldron, 2000; National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, 1979). This article identifies and discusses ethical dilemmas that arise in the conduct of prospective follow-up studies of addiction treatment.

2. Methods

To identify ethical issues in the conduct of longitudinal studies of addiction treatment, interviews were conducted with eight seasoned research staff (case trackers, field trackers, and interviewers) of Chestnut Health System’s Lighthouse Institute, who had collectively conducted more than 7,500 treatment follow-up interviews. The staff interviewed were selected for diversity in their gender (five male, three female), ethnicity (five African American, two Hispanic, one Caucasian), age (23 to 50), recovery status (three in recovery), years of experience working in follow-up studies (1 to 4), and role responsibilities (both line workers and supervisors). Following a review of the purpose of the study and securing voluntary oral consent to participate, staff members were asked to identify ethical dilemmas that had arisen in the course of their work and to offer suggestions on the best way to respond to such situations. Following the private 1-hour, one-on-one structured interviews, a 3-hour focus group of all staff was conducted in which the same questions were posed and discussed. All interviews were conducted during the regular workweek and did not require additional time from staff. The second author, who had no prior or subsequent supervisory relationship with the participants, conducted the individual and group interviews. The taped interviews were transcribed and analyzed by the authors to catalog the ethical issues and recommended responses. The issues chosen for inclusion in this article represent a mix of those identified as occurring most frequently and those that staff identified as being among the most difficult to handle. As an aid in presenting the findings of this qualitative study, we constructed brief vignettes to illustrate the various situations and ethical dilemmas encountered by the staff, taking care to alter potentially identifying information in the scenarios. Where an ethical issue was discussed in general without reference to a particular incident, a vignette was fabricated to illustrate the issue. We then synthesized the existing professional literature and material from the interviews into discussions of the vignettes. Legal consultation was sought regarding those situations involving both ethical and legal issues.

3. Results

The ethical issues identified in the individual and group interviews fell into seven broad arenas: (1) informed consent for research participation, (2) confidentiality and information disclosure, (3) relationship boundaries between study participants and research staff, (4) duty to warn/report responsibilities, (5) questions of autonomy and privacy, (6) compensation for research participation, and (7) data integrity.

3.1. Informed consent

Informed consent is the foundation of the ethical and legal relationship between a research organization and those who participate in its studies. The goal of this consent process is to assure that all candidates for study participation are fully informed of the exact nature of the study and, having been adequately briefed on all potential advantages and disadvantages of involvement in the study, are free to participate or refuse to participate in the study. For human participants’ research, the elements required for informed consent are clearly defined in federal regulations (45 C.F.R. §116 and 117). Ethical issues inherent in informed consent include the competence to provide informed consent, freedom from coercion in providing informed consent, the accurate transmission of information related to the potential risks and benefits of study participation, the alternatives to study participation, and the freedom to subsequently revoke informed consent and withdraw from study participation. Many of these issues are addressed in the design of longitudinal studies and in the review processes of Institutional Review Boards (IRB). There are, however, a wide variety of informed-consent issues that arise following the development of the study design and IRB approval.

3.1.1. Consent of minors

Vignette #1: An adolescent admitted to substance abuse treatment agrees to participate in a longitudinal study. When the parents are queried about the participation of their adolescent in the study and their own participation as collaterals, they state that they do not wish to participate in the study and do not want their adolescent to participate either. Are adolescents competent to provide their own consent for such participation? What ethical and legal issues are posed by this situation?

Federal confidentiality and privacy regulations (42 C.F.R. §2.14; 45 C.F.R. § 164.502(g) and 164.510(b)) defer to state law on the question of a minor’s right to consent to treatment and to release of information. Where minors have the legal authority under state law to enroll in treatment, they also have the right to consent to research related to that treatment (42 C.F.R. §2.14; 45 C.F.R. Part §46.402 and 46.408). In these states neither a parent nor guardian’s consent is necessary. This legal permissibility does not by
itself answer the question of whether such consent is ethical. The ethical prerequisites of informed consent or refusal demand that: (1) the minor be fully informed of the risks, likely benefits, and alternatives to proposed service procedures; (2) coercion is not utilized to achieve consent; and (3) the minor is mentally competent to consent or refuse (Group for the Advancement of Psychiatry, 1990). It is the third of these prerequisites that poses difficult ethical dilemmas with minors. The mature-minor doctrine holds that adolescents may be competent to provide consent but that criteria other than age must be used to determine such competence (Silber & Silber, 1996; Wilkinson, 1981). These criteria may be unmet due to the immaturity, psychological incapacitation, drug-related impairment, and coercive influences that are often present at the time of adolescent admission to treatment. Capacity for informed consent can be tested by having the adolescent read and discuss the consent form (Brody & Waldron, 2000) or by administering a quiz to test comprehension of the consent form (Grizzo & Vierling, 1978; McCrady & Bux, 1999).

Some investigators, including the authors, have taken the stance that parental consent should be required as a matter of policy for a minor’s participation in a follow-up study. The rationale for parental consent centers on concerns about the ability of substance-involved minors to fully understand the pros and cons of research participation at the point of intake into treatment and to offer competent consent for treatment. Capacity for informed consent can be tested by having the adolescent read and discuss the consent form (Brody & Waldron, 2000) or by administering a quiz to test comprehension of the consent form (Grizzo & Vierling, 1978; McCrady & Bux, 1999).

Some investigators, including the authors, have taken the stance that parental consent should be required as a matter of policy for a minor’s participation in a follow-up study. The rationale for parental consent centers on concerns about the ability of substance-involved minors to fully understand the pros and cons of research participation at the point of intake into treatment and to offer competent consent for participation (Hoagwood, Jensen, & Fisher, 1996). The potential threat to the autonomy of the adolescent posed by requiring parental consent may be overridden by the ethical mandate to minimize risk of potential harm from study participation. Inclusion of parents and guardians also has practical value due to their crucial role in gaining access to adolescent participants over the course of a study.

3.1.2. Changes in custody status of a minor

Vignette #2: At intake the custodial parent signed permission for the adolescent to participate in a longitudinal study. During the course of the study, legal custody shifts from the original consenting custodial parent to the other biological parent or other relative. How should the question of the adolescent’s continued participation in the study be handled, as well as communications with the new guardian, for whom there is no signed release?

In this situation, study personnel have no knowledge of the degree of information that has been communicated to the new custodian regarding the adolescent’s substance use, participation in treatment, or participation in the study. This raises issues related both to informed consent (for the study) and consents/authorizations for disclosure (to release confidential information). The adolescent should be contacted first to obtain written consent to release information to the new custodial parent/relatives. This is the minor’s right alone if he/she resides in a state that allows minors to consent to substance abuse treatment without parental consent. If the first parent was authorized to receive information based on the signed consent form then a member of the research team could contact this parent to determine whether he/she informed the current custodian about the child’s involvement in the study. If information was passed along to the new custodian, then obtaining a signed statement from the new custodian acknowledging consent to continue participation in the study would be advisable. Ethical issues surrounding informed consent can also arise when the legal custody of a minor shifts from the biological parents to a state child-protection agency. When there is a change in the legal custody of a minor, the original consent may be invalid and a new informed consent should be obtained for the minor’s continued participation in the study. It is best to negotiate access at the beginning of a study to those institutions that potentially could have physical or legal custody of participants during the follow-up period (Scott, 2004).

3.1.3. Use of locator information

Vignette #3: Mr. A. and Mr. B. are brothers who are involved in the same longitudinal outcome study. When the locator contacts listed for Mr. A. fail to locate him, one of the staff suggests the possibility of calling those contacts listed for Mr. B. to see if they can help locate Mr. A. What ethical or legal issues are raised by this suggestion?

While this strategy sounds like a reasonable approach to locate the lost participant, such a strategy would violate the promise made to Mr. A at the beginning of the study that the only people contacted would be those he specifically approved as locator contacts. This would also constitute a violation of the agreement with Mr. B regarding the purpose and use of his locator information. Contacting people beyond the scope of what was provided in the consent or for other purposes would be ethically inappropriate and violate federal confidentiality and privacy regulations.

3.1.4. Disclosure of locator information

Vignette #4: A participant being enrolled in a longitudinal study lists a wife and two girlfriends on his locator sheet. During a subsequent call to the wife to locate the participant, she asks who else has been contacted in an effort to locate her husband. How do you respond?

Great care must be taken to avoid disclosing to anyone either the names of other contact persons or the nature of information provided by these individuals or organizations. The ethical value of discretion dictates that such cross-communication is done only with the permission of the participant. One of the major ethical challenges in longitudinal research is that as the period of follow-up increases, the value of the original locator data decreases. When participants cannot be found using the original data, alternative methods such as the use of public records and databases are often helpful when locating lost participants.
The ethical issues involved in using such databases have not been well charted, and it is likely that sensitivities related to privacy of data issues will continue to evolve both in the culture at large and in the research community. It is best to include in the informed consent that research staff will access public databases in order to locate the participant for the interview.

### 3.2. Confidentiality

There are two sets of important federal regulations that researchers conducting longitudinal studies on substance abuse participants should be familiar with: the federal confidentiality regulations 42 C.F.R. Part 2 and the Privacy Standards promulgated under the Health Insurance Portability and Accountability Act (commonly referred to as the HIPAA Privacy Rule; 45 C.F.R. Parts 160 and 164). These regulations establish the conditions under which protected health information may be used or disclosed and contain specific provisions related to research. An authorization to disclose participant information must include all the required elements in order to be valid under both 42 C.F.R. Part 2, and the Privacy Standards Authorization is always required for use of protected health information for preparation of a research protocol, for use of protected health information of a deceased participant, and to follow up with a participant for research purposes, unless attempts to contact a participant for this purpose can be done without revealing to a third party the fact that the participant received substance abuse treatment services.

#### 3.2.1. Limits of disclosure

Vignette #5: A case tracker contacts a local agency representative listed on a locator form in an effort to locate a participant who is due for a follow-up interview. As the case tracker seeks information, the agency representative intersperses her own questions, e.g., “When was the last time you saw the participant? What is the last address you have listed for him? Which relatives and friends have you contacted?” What should be the response to such solicitations for information?

McCoy and Nurco (1991) provide a helpful principle to guide such interactions: One should never conclude an inquiry that leaves the individual contacted in possession of more information about a participant than they had when they were first contacted. Other researchers have framed this as a mandate to collect but never dispense information (Ribisl et al., 1996). Given that reciprocity plays a significant role in relationships, maintaining both confidentiality and trusting balanced relationships with collaterals (e.g., organizations, family members, friends) poses considerable challenge. When requesting information from someone like a parole officer, he or she usually expects a return of information. Rather than rebuffing such requests by reciting confidentiality regulations, it is best to reciprocate with general suggestions on how lost individuals might be located without disclosing confidential information on the participant in question or by offering to pass along a message in the event that the participant is located. Learning to solicit information and express appreciation for assistance without reciprocating with confidential information is part of the art of case tracking.

#### 3.2.2. Disclosure to parents about adolescent participants

Vignette #6: After failing to locate a runaway teenager through multiple family contacts, a case tracker finally locates the teenager (who has been taken in by some young adults). The case tracker conducts a 3-month follow-up interview and collects updated locator data to help locate the adolescent for his/her 6-month interview. The parents later call to ask the case tracker if he has seen their daughter, and if so, would he let them know where she is. How should the case tracker respond?

If state law allows an adolescent to apply for and receive addiction treatment, the adolescent’s location cannot be disclosed to the parents without the adolescent’s consent (42 C.F.R. §2.14). Federal regulations provide an exception for parental notification without the minor’s consent if there is reason to believe that (a) the minor, because of extreme youth or medical condition, does not have the capacity to rationally decide whether to consent to parental notification; and (b) the disclosure is necessary to cope with a substantial threat to the life or well-being of the minor or someone else. In this case, the case tracker must decide whether the living situation poses such a danger to the teenager. If not, the case tracker must maintain the teenager’s confidentiality.

#### 3.2.3. Police inquiries

Vignette #7: A study participant broke contact 3 months ago, and research team members have been unable to locate her. The participant, who is assumed to be in hiding due to an active arrest warrant, walks into the research office and asks to complete her interview. What legal and ethical issues are involved in research staff having knowledge of the whereabouts of people being sought by law enforcement authorities? How should study staff respond if they receive a call from the police asking when and where the participant was last contacted?

When individuals first begin working as case trackers or interviewers, they sometimes assume that there are laws requiring notification of the location of persons with outstanding arrest warrants. In fact, such disclosure would be a breach of the confidentiality that was part of the informed-consent process, as well as a breach of law. Federal confidentiality regulations provide only limited exceptions under which disclosures of participant information can be disclosed (e.g., child abuse or neglect, medical emergency). Acknowledgement of the participant’s study involvement or his/her whereabouts would constitute a breach of
confidentiality unless the participant had specifically approved such disclosure.

3.2.4. Inadvertent disclosures

Vignette #8: The ABC addiction treatment program conducts a longitudinal study in which interviewers use treatment facility phones to conduct the follow-up interviews. When a call is placed to the participant’s home, a visiting aunt sees on the caller ID screen that the call is coming from a substance abuse treatment agency and starts asking her nephew questions about it.

Vignette #9: When a participant is called for a follow-up interview but is not at home, a message is left asking the participant to call John at the ABC Center (or the treatment center number is left).

Vignette #10: Correspondence related to a study that is sent to the home of participants bears the following in small letters: “Funding for this project has been provided by the Center for Substance Abuse Treatment.”

All of these examples constitute ways in which the confidentiality of a research participant can be breached. Rigorous adherence to confidentiality rejects the assumption that persons with whom a participant lives or interacts are aware of the participant’s history of alcohol/drug-related problems, the participant’s involvement in treatment services, and the participant’s involvement in the research study. Inadvertent breaches of confidentiality can be avoided by having phones used for follow-up calling unlisted, listed in a neutral study name or legal alias, leaving no phone messages that could reveal the participant’s drug-use history or link the participant to an addiction treatment site, and by assuring the participant that no written communication (e.g., letters, brochures) will imply or state information about the participant’s drug use or treatment history.

3.3. Relationship boundaries

When ethicists speak of “relationship boundaries” in the context of research, they are referring to the demarcation between appropriate and inappropriate behavior in the relationship between research participants and the staff who conduct treatment and treatment-related research. Boundary management involves monitoring decisions that dictate the pace and degree of intimacy in the relationship between the professional and the participant. On a continuum of intimacy, boundary violations can occur as a result of too much attachment between participants and research staff (e.g., sexual exploitation) or too little attachment (e.g., disrespect, abandonment). Allegations of boundary violations are the most frequent source of complaints filed to ethics boards overseeing addiction treatment (St. Germaine, 1996). Relationship boundaries also constitute an arena of ethical ambiguity for the case trackers, field trackers, and interviewers who conduct longitudinal studies. Audiotaping the interviews is a good way of monitoring the boundaries, and shadowing during phone calls helps as well.

3.3.1. Self-disclosure and rapport

Vignette #11: John is a recovering addict working as an interviewer. He frequently shares his recovery status or part of his story as a way to make participants feel more comfortable. How might such self-disclosure help or hurt a research participant or the larger study? What guidelines should govern self-disclosure?

The issue here is not whether self-disclosure is an effective technique for building rapport between study staff and participants. The question is whether the self-disclosure by a case tracker, field tracker, or interviewer could cause injury to a study participant, research staff, the research organization, or the integrity of the research study. The factors involved in addressing this question are similar to those involved in the use of self-disclosure in addiction counseling (Chapman, 2000; Doyle, 1997). Carefully framed self-disclosures can be an effective technique of rapport building with research participants, but there are potential risks in the use of this technique. Self-disclosure by study personnel can contribute to the impression that the research site is a clinical setting within which the participant can receive assistance, heighten the discomfort of participants and decrease their willingness to participate in the study by inviting an increased level of intimacy, shift the focus of the interview from the participant to the interviewer, and lead to the selective deletion or embellishment of information provided by the participant.

At the most practical level, self-disclosure by the interviewer decreases the amount of time available to collect information from the participant or results in excessively long interviews that exact a burden on participants and decreases their willingness to participate in future interviews. Staff disclosure, if used at all, should be participant-focused, purposeful and strategic, brief, and appropriate for the research participant’s age, cultural background, and level of functioning. Once again, audiotaping interviews provides an effective method for monitoring staff adherence to standards.

3.3.2. Boundaries of competence and role clarity

Vignette #12: Raymond, a case tracker, is scheduled to conduct the 9-month follow-up interview with Ms. Mary S. Ms. S. appears unclean and disheveled as she enters Raymond’s office, and he notices that she has a dark blue bruise on the side of her left eye. Only minutes into the interview, Ms. S. begins to cry and shares with Raymond that she and her boyfriend are both using drugs again and that the fights that have long been part of their relationship are becoming more brutal. She says that it is only a matter of
time before one of them kills the other. She asks Raymond what he thinks she should do. How should Raymond respond to Ms. S.?

There are several factors that make solicitation of assistance to research staff from a research participant a common occurrence in longitudinal studies of addiction treatment. The participant being interviewed often presents with multiple life-problems that ebb and flow in frequency and intensity. The interviewers are good listeners and, as such, are easily mistaken for counselors. The content of the interview questions invites an exploration of many personal issues. Finally, interviewers in longitudinal studies may be among the most stable and constant people in the participant’s life. The staff that works in longitudinal studies can be involved in the lives of participants for 4 or 5 years—far longer than most counselors. All of these factors work to pull the interviewer into the counseling role.

There are multiple dangers in this vignette, including the threat to the safety of the participant, the partner, and the risk to the participant and interviewer resulting from interventions in situations for which the interviewer has not been trained. Underresponding or overresponding to such situations could harm the participant, partner, the interviewer, and the larger study of which the interview is a part. If the interviewer fails to respond, the imminent threat to the safety of the participant/partner could be sustained or even escalate. Becoming overinvolved could pose a threat to the participant and jeopardize her continued participation in the study. One goal in such situations may be for the interviewer to link the participant to needed resources without moving into full clinical engagement. Participants in crisis may need referrals and linkages to services, but great care must be taken to prevent the interviewer from becoming part of the intervention. In the face of such situations, meeting the goals of both the participant and the study can best be achieved by immediately seeking supervisory consultation.

A special category of concern related to boundary management arises in ongoing communications with participants who are in prison. Many of these individuals have burned all of their relationship bridges. Follow-up interviewers frequently encounter prisoners who want to use the interviewer to meet insatiable needs for emotional contact and support. Great care must be taken to prevent members of the research team from being seduced into this broader role, for the safety of staff as well as the protection of participants.

3.3.3. Dual relationship

Vignette #13: Malissa, who works as a case tracker and interviewer, is a longtime member of Narcotics Anonymous (NA) and continues to be involved in NA service work. She receives a call through NA to visit someone who left only a first name and a phone number. After setting up a visit with this person, agreeing to help transport the individual to some meetings, and act as a temporary sponsor, Malissa discovers that the person is a study participant and on her list of people to contact as a case tracker and interviewer. How should Malissa respond to this situation?

There are many problems that can arise from dual relationships in the treatment and research context, e.g., serving as interviewer as well as NA sponsor (Chapman, 1997; Doyle, 1997). There is a growing body of literature that can help those who are likely to experience such dual relationships, or “two-hatter” problems, as they have long been called in mutual-aid circles. This literature, which emphasizes the importance of avoiding dual relationships, comes from two sources: professional literature that addresses the special problems encountered by the recovering person working in a professional service role (e.g., Barker, 1996; Doyle, 1997), and guidelines for mutual aid group members who work professionally in the alcohol and other drug problems arena. (e.g., AA Guidelines, n.d.). Malissa should report the situation to her supervisor and the case should be reassigned.

3.3.4. Preexisting relationship

Vignette #14: Frank, an interviewer, is assigned to interview an individual whom he once dated. Should he accept this assignment? What should be the policy on serving as the case tracker or interviewer for someone with whom there is a preexisting relationship (e.g., family member, friend, lover)?

There is a danger that a preexisting relationship could affect the ability of the follow-up interviewer to competently perform his role, the comfort and safety of the participant, and alter the nature of the participant’s disclosures. To protect all parties in such situations, follow-up staff should immediately declare to their supervisor any preexisting relationship with a participant. It can then be determined whether that relationship could pose a problem and whether another staff person should be assigned to work with the participant.

Vignette #15: Lloyd is scheduled to interview a study participant for her third follow-up interview. Lloyd has been attracted to this research participant but has not said or done anything to express this attraction. Today, following his interview, the participant asks if she and Lloyd could get together some time. How should Lloyd respond to this invitation?

Several seasoned interviewers talked about how easily this situation can arise and the need to structure a response that clarifies the boundaries of the interviewer-participant relationship while protecting the feelings of the participant. Below is one seasoned interviewer’s response:

“We have to draw a line of appropriateness. We get people in here who have been abused in all kinds of ways. They are from a using world in which you never get something for nothing. We listen to them, we respect them, and we are
those boundaries that we don’t hurt their feelings and alienate them.”

Communicating clear standards via staff orientation can elevate the quality and integrity of staff relationships with research participants. Moreover, training regarding what is and is not appropriate in staff-participant relationships plus ongoing monitoring and supervision can minimize the potential for blurring boundaries.

3.4. Duty to report/warn

One of the most difficult areas of ethical conflict arises when the normal expectation of confidentiality is pitted against a participant’s potential threat to another person. These conflicts are embraced within a body of ethical standards referred to as “duty to report” or “duty to warn” and illustrated in the following vignettes.

3.4.1. Potential exploitation of a minor

Vignette #16: A member of the research team has finally made contact with a runaway adolescent who is now working for a circus. Either the adolescent has misrepresented his age or the circus company has ignored any concerns related to his underage status. Do members of the research team have any responsibility to report or otherwise intervene in this illegal employment?

Such situations pit the mandates of confidentiality against potential threats to the safety of the adolescent. Where such threats are not imminent, both ethical and legal requirements preclude intervention by the research staff. The research staff do not have a legal obligation to intervene unless it is determined that the adolescent’s situation qualifies as child abuse or neglect as defined by the applicable state law. Confidentiality restrictions would prohibit staff from reporting illegal employment unless child abuse or neglect is suspected and unless such information could be reported anonymously without identifying the adolescent as a recipient of substance abuse treatment services. The responsibility of the staff might be different if the adolescent was in an environment in which one or more adults were sexually exploiting him or her. In that case the risk of physical and psychological harm could pose a greater ethical responsibility to intervene than in the case of illegal employment. The latter situation might also call for mandated reporting via state laws and professional licensure and certification standards. The general guidelines for responding to such situations include seeking supervisory consultation, seeking clarification of federal and state legal and professional requirements, and documenting the decision-making process.

3.4.2. Allegation of unethical conduct at a study site

Vignette #17: During Ms. R’s 3-month follow-up interview, she reports to the interviewer that the counselor to whom she was assigned while in treatment made repeated sexual overtures to her and has called her three times since she left treatment to ask her out. What, if any, ethical responsibility does an interviewer have to act on reports of unethical conduct by treatment practitioners?

This vignette touches on many areas of potential harm: harm to the participant, harm to the reputation of the worker alleged to have committed such overtures, the reputation of the treatment program, and the reputation of the larger addiction-treatment field. It also raises the question of whether a member of a research team has a responsibility to respond to an allegation of illegal or unethical conduct by a worker at a treatment study site and, if so, what the exact nature of that responsibility is. Nearly all ethics texts affirm some level of responsibility. Potential responses to this situation include informing the participant that such behavior is a breach of counselor ethics and informing her of her rights to file a formal complaint (in some states, criminal charges), creating a clear standard that all such allegations reported in interviews should be brought to the attention of a supervisor, and contacting the counselor’s supervisor at the study site and informing the supervisor of the allegation without disclosing the identity of the participant. In some states sexual exploitation of participants is a criminal offense, and statutes sometimes include mandatory reporting requirements for various professional groups. Individuals working within studies also governed by ethical standards of professional licensing or certification boards may also be participant to mandatory reporting expectations.

3.4.3. Threats to safety

Vignette #18: During an interview, a research participant discloses that she has been losing her temper and physically striking her children and that she recently left her infant child unattended for 2 hours while she went to purchase drugs. What responsibility does the interviewer have to intervene in this situation? Would this responsibility differ if the participant reported their intentions to commit future harm to another person?

The federal confidentiality rule prohibits disclosure of participant communications except in a few very limited circumstances, including disclosures to report suspected child abuse as mandated by state law (42 C.F.R. §2.12(c)(6)). The interviewer may report the disclosure of abuse of a research participant’s own child or the direct observation of child neglect/abuse without violating the confidentiality law. If the interviewer is a mandated reporter under the applicable state law, there may be a penalty for failure to report the suspected abuse.

There is no exception in the confidentiality rules for disclosures of crimes unless the crimes were committed
on the program premise or against program personnel (42 C.F.R. §2.12(c)(5)). In general, the interviewer has no obligation to report disclosure of a past murder, rape, or arson. To report a disclosure of future intent to commit murder, rape, arson, or suicide requires a court order or a report without identifying the participant. However, if a clear and imminent danger to a particular person exists because a participant (a) has identified that person, (b) has a history of violence, (c) is capable of committing such violence, and (d) has communicated a specific plan to harm the particular individual, then the interviewer would be wise to err on the side of warning about the danger and reporting this to the appropriate authorities. Prior to doing so, the interviewer should seek supervision because such a warning would have significant legal, ethical, and clinical implications.

3.5. Autonomy/privacy/invasiveness

Research staff members sometimes walk a fine line between the information needs of a study and the autonomy and privacy of study participants. The next vignettes explore two of the more difficult issues in this area.

3.5.1. Privacy vs. pressure to achieve high follow-up rates

Vignette #19: Achieving high rates of follow-up in multi-year longitudinal studies requires a high degree of assertiveness (sometimes bordering on aggressiveness) in locating and maintaining contact with individuals and their collaborators. When does such assertiveness cross the line and constitute a breach of ethical conduct?

There are several universal values that can help reconcile respect for study participants with the pressure felt by research staff to generate high follow-up rates. The value of autonomy dictates respect for a participant’s right to terminate their involvement in the study. The value of competence demands that staff accurately communicate the effect that disengagement will have on the participant and the larger study of which he or she is a part. The value of nonmaleficence calls for staff not to harm study participants by being overly invasive in their efforts to assure study participation. (Such harm could accrue to the participant from a frequency or persistence of contact that borders on harassment or stalking or in having persons listed on the locator form become hostile toward the participant because of such frequency or persistence.) None of these values precludes using an assertive approach to locate study participants and encouraging their continued participation in a study. Seasoned interviewers recommended the following responses to this dilemma:

1) During the initial informed-consent process convey to the participant the methods and intensity of follow-up procedures that will be employed.

2) Assuming that (a) resistance to participating in a research study is normal, (b) motivation for participation varies widely from participant to participant, (c) there are different styles of communication that will need to be matched to particular participants/families, and (d) participants should be matched to the available staff with whom they have the best relationship and feel most comfortable.

3) Communicating that going “above and beyond” to locate someone is an indication of the participant’s importance to the study and the larger goal of improving the quality of addiction treatment.

4) Assessing the timing of every point of contact, sensing when it is not a good time for the participant/family and quickly agreeing to get back at a more convenient time.

5) Maintaining the principle that no one can speak for the participant but the participant.

It is difficult to convey the fluid nature of the relationship between research staff and study participants over the course of years. It is this very fluidity and ambivalence that makes it difficult to accurately read the intent of a particular participant on a particular day.

3.5.2. Respect

Vignette #20: Susan, a follow-up interviewer, contacts a study participant to schedule his next interview. The participant informs her that he is dying and has only a few weeks to live. How should Susan respond?

The ethical question here is what importance, if any, does the participant now place on his participation in the study? The authors have encountered participants who wanted to complete interviews under these very circumstances for motivations ranging from a need for the interview fee for burial to feeling like they still had something of value to contribute that could help others. Staff involved in longitudinal studies struggle every day to define the boundary between maintaining respectful, noninvasive relationships with participants and methods that cross ethical boundaries in the pursuit of high follow-up rates.

3.6. Compensation

There are a number of ethical issues that can arise in the compensation of research participants. First, a high level of compensation could be a source of hidden coercion, influencing the participation of indigent persons (or persons in need of money to stave off drug withdrawal) who might otherwise refuse participation because of risks or discomfort associated with a particular study (McCrady & Bux, 1999). Second, concerns are sometimes raised that providing cash to addicts as part of longitudinal research might influence the very outcomes being measured.

Vignette #21: When Robert, a follow-up interviewer, calls a participant to schedule his next interview, the participant’s
sister answers the phone. When she discovers who is calling, she launches into a tirade that could be summarized as follows: ‘The last time my brother went to your office you gave him money that he immediately used to buy drugs. You of all people should know that you don’t give cash to a drug addict!’ How can the use of financial remuneration for research participation be managed to minimize potential harm?

Financial incentives are frequently used to compensate participants for their time and travel when participating in longitudinal research, even though motivation for such participation often goes beyond the receipt of money (Fry & Dwyer, 2001). Festinger and colleagues’ findings (2004) suggest that the level of research compensation does not contribute to the risk of relapse and that providing cash is more respectful of study participants, produces higher rates of follow-up contact, and generates higher levels of satisfaction related to research participation. Cottler, Compton, and Keating (1995) reported similar results.

3.7. Data integrity

Many ethical issues can arise that threaten the integrity of research data. These range from interviewing styles that compromise the ability to objectively collect data to outright fabrication of research data.

3.7.1. Interviewer neutrality

Vignette #22: A study participant, drug free for 3 years, reports in her interview today that she has resumed daily use of heroin. How should the interviewer respond to this disclosure?

This vignette elicits the importance of the neutrality of the interviewer. The primary ethical duty of interviewers is to conduct themselves in ways that enhance the integrity of the data they are collecting. That requires a high degree of neutrality to the information reported by the participant. By expressing or otherwise conveying disappointment, disapproval, sorrow, anger, or other emotions, the interviewer risks shaping the kind of disclosures a participant is willing to make. There are many people trying to influence the conduct of the participants’ lives. The job of the interviewer is to collect the most objective report possible on the post-treatment status of the participant. To do anything other than that, except in the most extreme situations, is to abandon the role of researcher and become part of the intervention being evaluated. Balancing a nonjudgmental demeanor with appropriate levels of interest and concern is crucial to enhancing a participant’s willingness to continue their participation over the long course of a study.

3.7.2. Potential misrepresentation of data

Vignette #23: A follow-up interviewer reports that she has scheduled 80% of the participants assigned to her for 6-month interviews, but when her supervisor checks the case files, she finds documented appointments for only 30% of the cases assigned to the case tracker. How should the supervisor respond?

The integrity of scientific research is founded, in part, on the integrity of the raw data that is at the heart of the endeavor. Such integrity must be assured rather than assumed. Breaches in data integrity can occur through outright dishonesty or through subtle forms of cutting corners in data collection and recording. We have found the following strategies helpful for assuring the integrity of study data: verifying the identity of those being interviewed using photographs taken at the beginning of the study, randomly verifying the written records of phone and face-to-face contacts reported by research staff, and confirming the identity of participants interviewed in the field via telephone contact between the participant and a supervisor to verify that the right person has been interviewed.

4. Discussion

4.1. Strategies to enhance ethical decision-making

We have found several strategies useful in elevating the ethical conduct of longitudinal research studies. First, it is important to identify potential ethical issues that could arise within a particular study and to proactively manage these risks by refining the research protocols prior to study implementation. The most important ethical foundation is assurance that the study addresses an important rather than trivial research question and is well designed and executed.

Second, research staff benefit from being oriented to the ethical terrain of a particular study so that they can recognize and respond to ethical issues as they arise. Ethical sensitivities and ethical decision-making can be enhanced through rigorous orientation, competency-based training, and group debriefing of ethical issues that arise in the day-to-day conduct of longitudinal studies.

A third strategy for elevating ethical conduct is to assure access to consultation by encouraging staff to seek advice from tenured staff and to bring difficult ethical dilemmas to the attention of a supervisor in a timely fashion. The fishbowl nature of daily activity within many research studies—through which there is a high degree of interaction between staff and supervisors—enhances peer and supervisory consultation process.

A fourth strategy is to document ethical dilemmas and ethical decision-making. It is helpful to utilize a critical-incident reporting process through which events out of the ordinary (any incident calling for a divergence from normal procedures) are documented and reviewed by supervisors. Reviewing these critical incidents in regularly scheduled staff meetings is a valuable tool to heighten ethical sensitivities.
It is our hope that the vignettes and discussions presented in this article will serve as a training tool for those directly involved in prospective studies of addiction treatment. The vignettes could be presented for small-group discussions using various models of ethical decision-making to facilitate their resolution. White and Popovits (2001), for example, propose a three-step model of ethical decision-making that can be used as a tool for analyzing complex ethical dilemmas within the addictions field. Their model poses three questions that elucidate the potential complexities of such dilemmas: (1) Who stands to gain or be harmed in this situation and what is the degree of potential harm? (2) Are there any universal or culturally specific values that apply to this situation, and what courses of action would these values dictate? (3) Are there any existing laws, regulations, organizational policies, or historical practices that apply to this situation?

4.2. Summary

This paper has identified some of the ethical issues that arise in the conduct of longitudinal research of addiction treatment and outlined strategies to heighten ethical sensitivities and ethical decision-making. The review includes issues related to informed consent, confidentiality, relationship boundaries between research participants and research staff, duty to report responsibilities, autonomy and privacy, compensation for research participation, and data integrity. Strategies for elevating this level of ethical practice include care in research design; the development of policies on competence for informed consent, the exceptions to confidentiality, and duty to report or warn; staff orientation and training on ethical/legal issues; peer and supervisory consultation; and critical-incident debriefing and documentation.

There were several limitations to this study. First, the paucity of literature on ethical issues in longitudinal studies of addiction treatment precluded constructing a more precise measurement of the frequency of particular types of ethical dilemmas. The qualitative approach of asking open-ended questions about the experiences of seasoned interviewers was able to elicit a large spectrum of ethical issues upon which future studies might be based.

The findings of this study may be limited to the particular types of participants most frequently seen in the studies conducted by the Chicago office of the Lighthouse Institute. These studies focus on outcomes of urban participants treated in publicly funded addiction-treatment programs. Participants in our studies have exhibited high levels of problem severity and complexity, numerous environmental obstacles to recovery, and low levels of family and social support. It is possible that these characteristics influenced the types, frequency, and severity of ethical dilemmas that were identified in this study. Other research settings where participants present with different demographic and clinical characteristics might encounter ethical dilemmas that are qualitatively different than those reported here. It is also possible that ethical dilemmas are defined as much by the characteristics of the research staff as by the characteristics of research participants. Future studies could define the extent to which the nature of these dilemmas varies in tandem with the characteristics and vulnerabilities of these two groups and the extent to which strategies to manage ethical dilemmas may require a high degree of individualization across research settings. In spite of such possible nuances, we anticipate the emergence of widely applicable strategies for elevating the ethical conduct of longitudinal studies of addiction treatment. This study confirms the interlocking responsibilities that are crucial to achieving this goal. Senior scientists and project managers have a responsibility to reflect sensitivity to ethical issues in their research designs and their utilization of IRB processes. Supervisors have a responsibility to orient, train, model, and monitor ethical decision-making, as well as provide a safe environment in which ethical issues can be brought into peer and supervisory consultation. Case trackers, field trackers, interviewers, and other support roles have a responsibility to identify the presence of ethical dilemmas and to seek assistance to resolve such dilemmas. We foresee a day in the not-too-distant future in which role-specific ethics training will be required for everyone in the addictions field who is involved in clinical research.

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