RESEARCH REFLECTIONS
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The Ethics of Applied Research with Individuals with Addictions

Colin P. K. Perrier, MSc, (PhD Candidate)
Law and Mental Health Program
Centre for Addiction and Mental Health, Toronto, Canada

Holly Etchegary, PhD
Clinical Epidemiology, Faculty of Medicine
Memorial University, Newfoundland, Canada

Nadia Palarchio, MA,
Community Support and Research Unit
Centre for Addiction and Mental Health, Toronto, Canada

Peter Snelgrove, MA
Stonehenge Therapeutic Community, Toronto, Canada

ABSTRACT

Myriad ethical issues are inherent in applied research involving individuals with addictions. Formal guidance from governing bodies for research with this specific vulnerable population is needed; however, it is presently all but absent. The current paper highlights the interrelated issues of dual relationships, incentives/inducements, and informed consent that occur when this research is conducted. Given the varied nature of addiction in terms of severity and likelihood of relapse, a focus on the unique risk for each participant is recommended. It is advised that applied researchers be cognizant of these important ethical issues, develop protocols, and ensure that research assistants have appropriate training.

Key words: research ethics; applied research; ethics; incentives; dual relationships; applied research with individuals with addictions; addictions research ethics.

Ethical issues are inevitable when conducting applied research with individuals with addictions. The quandaries discussed in this paper pertain to dual relationships with clinician-researchers, the use of incentives/inducements, and the ability of the client to provide informed consent. First, a discussion of available ethical guidance is provided.

The Ethical Climate – Standards and Practices

Ethical research practices in Canada are guided by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TPS: CIHR et al, 1998). This policy provides direction with respect to many aspects of research with human participants (e.g., minimal risk, informed consent, confidentiality, and conflicts of interest). Still, these guidelines do not adequately inform practices in the arena of addictions research, especially with respect to dual relationships and the use of incentives. With respect to incentives, Research Ethics Boards (REB) are instructed by the TPS to consider the economic situation of potential participants and to caution against a payment structure that might unduly induce individuals to join or remain with a study. Similarly, the Canadian Code of Ethics for Psychologists (Canadian Psychological Association, 2000), while commenting on the issues, does not provide enough direction. The standards for the *Avoidance of conflict of interest* indicate that one should:

III.31: Not offer rewards sufficient to motivate an individual or group to participate in an activity that has possible or known risks to themselves or others. (Canadian Psychological Association, 2000, p. 26)

III.33: Avoid dual or multiple relationships (e.g., with clients, research participants, employees, supervisees, students, or trainees)

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and other situations that might present a conflict of interest or that that might reduce their ability to be objective and unbiased in their determinations of what might be in the best interests of others. (Canadian Psychological Association, 2000, p. 26)

With respect to attaining consent, also relevant are statements I.27 (Take all reasonable steps to ensure that consent is not given under conditions of coercion, undue pressure, or undue reward) and I.28 (Do not proceed with any research activity, if consent is given under any condition of coercion, undue pressure, or undue reward). Again, these statements provide a framework, but they do not provide the direction needed in terms of providing incentives and managing dual relationships with addictions clients.

With respect to program evaluation, the Canadian Evaluation Society (CES) has recently (April 3, 2008) published its ethical guidelines and, with these, a comparison to the guidelines outlined by evaluation associations in other countries (CES, 2008). Still, these guidelines make no reference to issues of payments to participants or dual relationships. Further, although CES is the professional association for evaluators in Canada, there are currently no standards in place that govern practice as an evaluator, nor is there any type of accreditation as a professional evaluator (although this process is underway). Further, the educational backgrounds of individuals working in the field of evaluation are quite disparate. As such, it would behoove professional evaluators and others involved in applied research to avail of additional training in research ethics in order to supplement the available guidance from their regulatory body or association. Such training may involve accessing free online tutorials, such as those available through the National Institutes of Health (http://www.nih.gov/) or the Interagency Panel on Research Ethics (www.pre.ethics.gc.ca), or reviewing the ethical guidance provided by such governing bodies as the Office of Human Research Protections in the United States (http://www.hhs.gov/ohrp/) or similar governing bodies in other jurisdictions.

Clearly, specific guidelines for practice are lacking and further evidence-based ethical direction is necessary to protect participants and ensure quality research (Anderson & Dubois, 2007). Of course, REBs may provide specific guidance regarding these issues; however, the applied research and applied researcher for which this paper is intended may not always be affiliated with an institution which has an REB. The following sections address some of the primary considerations for such guidelines.

The Ethical Problems: Dual Relationships – The Clinician-Researcher

A clinician-researcher is an individual who provides direct clinical services and conducts research (see Yanos & Ziedonis, 2006). Within these roles, a number of dual relationships are prevalent in applied research with substance users.[1] Evans and Hearn (1997, citing Pope, 1991; Sonne, 1994; Valentich & Gripton, 1992; Younggren & Skorka, 1992) suggested that "a dual relationship in professional practice occurs when a practitioner is in another significantly different professional or non-professional relationship with one or more of his or her clients" (p.53). With respect to a clinician also acting as a researcher, Evans and Hearn (1997) suggested only that there is a potential for a dual relationship. Of course, such potential is realized when the clinician asks the client to participate in a research project.

When considering the concept of professional boundaries, Gutheil and Gabbard (1993) discussed a distinction between boundary crossing and boundary violation. The authors suggest that boundary crossing occurs when roles have been changed wherein the professional helper-client relationship may have moved in ways that reflect a friendship, or an alternative relationship not akin to the original professional roles and practices. The authors define boundary violations as occurring when exploitation of the client exists. The position in the present paper is that the situation in which a clinician participates in the recruitment of a research participant exemplifies a boundary crossing and should thus be avoided as it extends the limitations of the helper-client relationship.

Within the concept of dual relationships, a discussion around power imbalances is also warranted. It is the power differential that contributes to the influence that the clinician has over the client (Evans & Hearn, 1997), and we must question whether this power differential is contributing to the client's decision to participate in a research study in which he/she would not have otherwise participated. Table 1 presents types of dual relationships that are present in applied research and illustrates the power imbalance through the recruitment questions that may be asked of clients. In each of these situations, it is evident that the client may experience some pressure to participate. One cannot be certain that the client would have participated without such influence, so the clinician should take into careful consideration his/her potential influence and its impact on the client.

Table 1:
Recruitment Questions Posed to Addicton Clients

Recruiter	*Recruitment Question Posed to Addictions Client*
Clinician-Researcher	Will you participate in my research study?
Clinician	Will you participate in my colleague's research
Researcher	I was given your name by your clinician. Will you participate in my research?
Program Manager/Staff	Will you participate in the evaluation of the program in which you are currently enrolled?

The conflicts that are presented within the dual roles of the clinician-researcher in applied research are commonly summarized into financial conflicts of interest and those arising from the opposing agendas inherent in each role, namely, beneficence on the part of the clinician (e.g., acting in the best interest of the client) and scientific autonomy on the part of the researcher (e.g., conducting scientific research using the appropriate rigour) (Yanos & Ziedonis, 2006).Clinicians often have good reason to participate in research involving human participants. Reasons may be related to professional promotion and reputation, as well as partnerships with

third parties, such as pharmaceutical companies. Moreover, Yanos and Ziedonis (2006) present the argument that within applied research those with direct clinical exposure have the advantageous position of understanding the most relevant research that would contribute to issues 'on the ground'.

Thus, the direct and subtle ways in which clinicians influence the recruitment of clients as research participants challenge a position that suggests that clinicians completely avoid any role in the recruitment of research participants. Rather, it is suggested that clinician-researchers maintain extreme caution when these roles cross. Yanos and Ziedonis (2006) present an effective approach for clinician-researchers to integrate their dual roles. Specifically, the authors suggest that clinician-researchers develop an 'integrated identity' toward dealing with conflicts of interest such as dual relationships. The approach entails that clinician-researchers be aware of themselves and their ethical responsibility to the individual client and take steps to ensure that relationships with participants are formed in ways that minimizes the chance of therapeutic misconception. The authors also make the point that although self-awareness and education may still leave room for bias leading to exploitation and or poor science, these key steps are effective in putting forth the appropriate context for the clinician-researcher to use sound ethical judgment.

In the case where this ethical judgment leads to a conclusion that recruiting participants may cause irreversible harm to the existing relationship, then the clinician should avoid any role in the recruitment of participants for a research study. This may include engaging in a discussion of research projects, distributing research information, and permitting a recruitment poster in his/her office. In each of these cases, the client may perceive that the clinician views participation favourably and is therefore, if even minimally, influencing participation. As such, clients are participating with the underlying expectation that they will be pleasing their clinician because of "prosocial" behaviour. In many cases, however, this can not be avoided as the research cannot proceed without the clinician bridging the gap between a researcher and the research participant. Moreover, the benefit of the research may extend beyond any potential harm which is created through a boundary crossing. At the very least, it is important for these issues to be considered when research protocols are being developed and implemented.

The Ethical Problems: Dual Relationships – The Qualitative Researcher

Dual relationships and boundary crossings may also occur in the context of a qualitative research interview (Bourdeau, 2000). Qualitative research, as compared to quantitative research, relies heavily on interview methodology and may involve lengthy sessions (e.g., 2 hours) crafted to facilitate maximum disclosure. Bourdeau (2000) reviewed literature that suggested many similarities between the qualitative researcher-participant relationship and the clinician-client relationship. Although the relationship between clinician and client is somewhat unique, the time that a researcher engages with a client during a qualitative interview also has the potential to test boundaries. For example, if the qualitative researcher does not remain attentive to maintaining his or her boundaries, he or she may over-disclose personal issues when in dialogue with a client in an effort to enable a client to relate to a research question or bring meaning to a research question.

It is the position of the authors that the nature of the disclosures made in interviews with individuals with addictions necessitates that qualitative researchers make every effort to limit the potential for boundary crossings; specifically, the qualitative researcher should avoid assuming roles that resemble those of a clinician. As the qualitative interviewer employs many of the same interviewing skills (e.g., reflection, probing, reframing, summarization) as the clinician in an effort to achieve similar goals (e.g., rapport, insight into client emotions, thoughts, and motivations, and identification of problems) there is a high potential for roles to become blurred. Moreover, the fact that qualitative researcher training is often minimal, it cannot be assumed that competence will be exercised in dealing with the complex diversification of emotions that may surface during the course of an interview. Further, if the research employs a longitudinal design, the potential for dual relationships and boundary crossings is larger and thus requires more skill to avoid. In summary, research interviews with individuals with addictions could result in dual relationships because of a possible power-differential, the possibility of a lengthy interaction, and a potential for non-immediate termination of the researcher-participant relationship, especially in the case of longitudinal studies.

The Ethical Problems: Incentives and Inducements

The ethical issues surrounding dual relationships are exacerbated when incentives are considered. Unfortunately, however, very little has been published regarding the ethics of paying substance users to participate in research. This is of particular concern given this is a population for which payment for participation may trigger relapse (Seddon, 2005). Seddon (2005) reviewed research suggesting that financial incentives (including food vouchers) place individuals with addictions at risk because they are likely to use this compensation to fund the addiction. Similarly, Shaner et al (1995), in an evaluation of 105 individuals with cocaine dependence, noted a strong temporal association between support payments to drug users and substance abuse relapse. This suggests that even payment to individuals in addiction recovery may be creating undue harm. Indeed, many clients in treatment for substance abuse problems consider money a precipitating factor with respect to relapse. Moreover, as noted by Fry, Hall, Ritter, and Jenkinson (2006), we must especially attend to the undue influence of incentives on individuals experiencing withdrawal symptoms, intoxication, or related psychosis.

Still, if incentives were so detrimental to individuals with addictions, one would expect larger incentives to have a greater negative impact. Yet, Festinger et al (2005), in a well-devised controlled study on the matter, found that neither the method (cash or gift certificate) nor the amount ($10, $40, or $70) of payment had an impact on perceptions of coercion or subsequent rates of drug use. Payment amount was, however, associated with increased rates of participation. Still, as with the general population, incentives are not the only reason that individuals with addictions participate

in research (Fry et al., 2006). Fry et al noted that individuals with addictions participate in research for a variety of reasons: "citizenship, altruism, personal satisfaction, drug user activism, and to obtain information" (p. 24). Thus, this research suggests that incentives are beneficial for recruiting participants (Fry et al., 2006; Ritter et al., 2003) and maintaining longitudinal samples (e.g., Festinger et al., 2005). In summary, payment may result in relapse for some (Seddon, 2005), which is a definitive risk to participant wellbeing. Ultimately, individuals with addictions have the right to receive the same benefit from research as is received by other research participants (Fry et al., 2006).

It is evident that payment acts as an incentive; however, the issue of inducement is somewhat less clear. Of relevance here is the economic situation of this target group. Many substance users are recipients of social benefits, and therefore, have limited resources. As noted, REBs are asked to consider the economic situation of participants when examining financial incentives (CIHR et al., 1998). This consideration is nowhere more relevant than with marginalized mental health consumers. As such, financial incentives are more likely to act as an inducement with this population than with the general population. As Marson, Savage, and Phillips (2006) noted in a review of literature on ethical concerns related to the financial capacity of individuals with serious mental illness, "a monetary payment of $50 may represent a full month's personal spending money for the person with severe mental illness, but only a modest recompense for his or her typical adult counterpart" (p. 89). It is troubling then that a survey conducted by Ripley, Macrina, and Markowitz (2006) demonstrated that REBs examining clinical research proposals did not, in fact, consider participant income as important in determining the appropriateness of different payments. Nonetheless, REBs need to be aware of the link between incentives and drug use for individuals with addictions, and pay particular attention to the economic situation of the participants. If relapse is likely, then it is not ethical to facilitate this relapse.

It follows that REBs and researchers should not work under the naïve assumption that the addictions population is somehow a homogenous group that shares the common thread of substance dependence. There are marked differences across substances in terms of behaviour and impact on reasoning. As such, it is speculated that the impact of incentives and dual relationships will vary across individuals, depending on the drug being used and the severity of the addiction. Therefore, to adequately determine and manage the risk to participants, a thorough screening of potential participants and their motives is warranted. A better understanding of risk for each specific participant will undoubtedly have an impact on the informed consent process. Given the mixed findings in the reviewed literature, it is clear that we do not yet know enough about the effect of incentives on relapse and other negative outcomes. So, until which time as a larger and more conclusive body of evidence is developed, it seems prudent to proceed with caution and inform individuals with substance abuse problems about these potential harms.

The Ethical Problems: Informed Consent

The condition of informed consent requires that: 1) the individual is given enough information to make the decision of consent, 2) the individual understands the information, 3) the individual has the capacity to consent, and 4) the consent is voluntary (Faden et al., as cited in Loue & Ioan, 2007). The preceding discussion of inducements and relapse risks draws into question whether or not individuals with addictions are capable of meeting the requirements of informed consent. Fry et al. (2006) noted that "the main ethical questions about subject payments relate to their potential impact upon voluntary consent (i.e., inducement or influence), and the related issue of how prospective participants evaluate the personal risks, harms and benefits from research." (p.23). It does not appear then, based on the reviewed literature, that individuals with addictions are currently being offered adequate risk information to permit consent. At the very least, participants should be provided with additional information during the consent process. Applied research conducted by the first and third authors has included the following statement in the consent form: "Some evidence suggests that participating in research for financial compensation is associated with an increased risk of relapse."

Research Quality

Finally, we must consider the purpose and quality of the research that is being conducted with individuals with addictions. We must consider that applied research with individuals with addictions has important public health implications and therefore obtaining a representative sample is essential. With respect to the evaluation of programs that facilitate recovery, it is essential to ensure participation of the clients being served. It is often the case that these programs may be piloted with a limited number of individuals and therefore methods to increase participation rates are important. The experiences of these individuals speak to the value of the program/intervention and have direct effects on program continuance and expansion. As noted in a review by Fisher (2004), certainly, the validity of such studies is questionable if participation rates are minimal.

Another important issue with respect to the quality of research with individuals with addictions relates to the longitudinal nature of much applied research. In making the case for the value of a program/intervention, it is essential to demonstrate the long-term benefits of these programs. Therefore, including incentives is key to ensuring that participants maintain contact with researchers and that they notify the researchers when changes of address occur. This is especially relevant for mental health and addictions consumers who are likely to be transient and suffer relapses. Fry et al (2006) reviewed research that supported the contention that incentives improve recruitment and retention. Still, as noted, consumers should be informed of the risks associated with such incentives.

Conclusions and Recommendations

The prior discussion has highlighted some of the ethical issues relating to research with individuals with addictions. It is clear that attention to these ethical issues, while growing, is still

extremely limited. REBs, professional associations, and the clinical and research professionals in the field are in a position to provide leadership and guidance in this area. In the case of vulnerable populations, such as individuals with addictions, evidence-based decision-making is necessary (Anderson & DuBois, 2007). It is clear that dual relationships exist (Evans & Hearn, 1997), that incentives increase participation and are linked to drug use (Seddon, 2005), and that participants may not fully understand the risks associated with participation and are therefore not meeting the requirements of informed consent (Fry et al., 2006). Therefore, REBs should require that researchers demonstrate an understanding of these issues and have in place steps to minimize the risk of relapse.

However, in the absence of formal guidance, the onus is placed on the applied researcher to ensure that participants and research assistants are informed of the potential risks. Research assistants who will be interviewing substance users should be trained to recognize dual relationships and to be aware of the power differential that exists with clients/participants and the potential hazards involved with paying participants (e.g., traveling with money to and from interviews). Further, protocols should be developed for situations wherein the participant may be experiencing withdrawal symptoms, intoxication, or related psychosis. Protocols should cover, for example, appropriate meeting places/times, methods of payment, emergency contact information, and training in recognizing adverse symptoms. This would help ensure the safety of the participant and the researcher. REBs should require that such training and protocols be in place prior to study commencement.

Researchers should also be conscious of the fact that many clinicians working with individuals with addictions have not received ethics training and may not be aware of appropriate research ethics or the intricacies of related dual relationships. Therefore, providing direction to clinicians (for example, on not recruiting participants) may be necessary. Likewise, clinicians should be aware that many individuals who conduct applied research, such as program evaluation, have not received adequate training in research ethics and may also not fully understand the problems associated with dual relationships. These problems may be partially addressed if all individuals who are involved in collecting data from clients be advised to take one of the available online ethics courses. It is important to note that many of the projects which are the focus of this paper do not undergo REB review as they are considered quality assurance or because they are being conducted regarding a program or treatment facility that is not university affiliated. As such, the onus rests with the applied researcher/clinician to consider and address these education gaps.

Further, as noted, a more detailed screening of participants is necessary in order to minimize risk. This screening should inform the researcher about the availability of financial resources, severity of addiction, sources of emotional support, and motives for participation. The researcher should not permit the participation of individuals for whom payment is a primary motive and/or the purchase of drugs with this payment seems likely. However, it is also important to consider that research participation could be seen as a means to earn money without resorting to crime; thus, a possible form of harm reduction. An alternative approach may be to build research participation into the program design and funding, thereby requiring that participants of programming be participants in related evaluation research. Beyond these methods, applied researchers should lobby professional associations and REBs to attend to, and provide further guidance, on this matter.

As a final note, the reader is also cautioned that, in a mental health setting, it is difficult to disentangle the addictions population from other clinical populations. As such, attention to the ethical issues relevant to research with forensic clients, clients with developmental disabilities (Fisher, 2003), geriatric clients (Moye & Marson, 2007), and clients with severe mental illnesses (Marson, Savage, & Phillips, 2006) is important. Concurrent and dual diagnoses are prevalent and, therefore, the applied researcher must ensure sound ethical practice when dealing with these vulnerable populations. In the absence of action from other groups, the applied researcher should be cognizant of ethical practice with individuals with addictions and the outlined nuances of dual relationships, incentives, and informed consent.

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Endnotes

[1] Note that issues of dual relationships are important for all areas of applied research in mental health settings, not just for substance users.

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Address for Correspondence:

Colin P. K. Perrier, M.Sc. PhD (C)
Manager(A), Program Development & Evaluation
Law and Mental Health Program
Centre for Addiction & Mental Health (CAMH)
1001 Queen Street West
Toronto, Ontario, Canada
M6J 1H4

e-mail: *colin_perrier@camh.net*