# ETHICAL ISSUES ARISING WHEN PLANNING AND COMMENCING A RESEARCH STUDY WITH CHEMICALLY DEPENDENT PREGNANT WOMEN

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# **ABSTRACT**

A good deal of qualitative research, particularly in the health sector, involves accessing vulnerable groups of people. One such group is chemically dependant pregnant women. Accessing and interviewing chemically dependent pregnant women presents significant ethical challenges which are compounded by the vulnerability of this group, who often experience feelings of guilt, mistrust of health professionals, and a myriad of related health problems which can impact on their unborn child. This paper explores some ethical issues in relation to access, informed consent, the interview process, potential exploitation, invasion of privacy, and confidentiality related to information obtained and the publication of results. Ways in which these issues can be addressed without compromising the research are discussed.

# INTRODUCTION

his paper discusses ethical issues, which have arisen in the early stages of a study aimed at identifying and exploring the needs of a group of English speaking, chemically dependent pregnant women and the degree to which a multi-disciplinary team working within a specialised antenatal clinic meets these needs.

Research involving vulnerable groups, such as lesbian and gay men's experience of nursing care (Platzer 1997), the help seeking behaviours of alcohol dependent and problem drinking women (Smith 1992), and the sexual experiences of women with learning disabilities (McCarthy 1998) have identified significant ethical issues relating to the 'duty of care' of the researcher to protect the rights of disadvantaged groups in all facets of the research. Similar ethical issues to those identified in the above studies have arisen in the research described involving chemically dependent pregnant women. This paper will outline the research approach, provide background to the study, focus upon identifying why a study of chemically dependent pregnant women presents specific ethical challenges in its planning and process and describe the way in which these might be managed. Challenges include issues relating to access, informed consent, relations between the researcher and researched in the interview process and publication of results.

#### RESEARCH DESIGN

An ethnomethodological approach, as articulated by Garfinkel (1967) and adapted by Holstein and Gubrium (1994), was chosen as the most appropriate methodology to identify and explore the needs of chemically dependent pregnant women. While similar to ethnography, ethnomethodology differs in the sense that it sets aside the notion that behaviour is rule governed, or motivated by shared values and expectations, and pays close attention in analysis to how talk is considered as the action through which local realities are accomplished.

A feminist theoretical perspective underpins the methodology. It is generally agreed that the principles of feminist research, described by Grbich, who draws on the ideas of Stanley (1990) and Oakley (1981) are as follows: Feminist research places a focus on the 'social constructedness' of gender, accepts that women are oppressed (to varying degrees); attempts to be egalitarian, non-exploitative and emancipatory; exposes the researcher's experiences and emotions and addresses issues of 'power, honesty and ownership' (Grbich 1999, p.53). A feminist perspective promotes open reciprocal interactions between the researcher and the researched with a balance created between potential harm and potential good, confirming the accuracy of the study findings by paying particular attention to critiquing designs, analysis and conclusions (Seibold et al 1994). The philosophy of feminist researchers is succinctly described by Punch (1994, p.83) as: 'You don't rip off your sisters'!

The study employs participant observation of clinical encounters between the women and the staff of the clinic, including midwives, social workers, administrative staff, interviews with the women attending for care at a specialised antenatal clinic, and access to medical records. Ethical clearance was gained from the Australian Catholic University Human Research Ethics Committee and the Mercy Hospital Research Ethics Committee, where the specialist clinic is situated. The data collection phase is in its early stages and women interviewed so far are at least second generation Australian.

# BACKGROUND TO THE STUDY AND ISSUES IMPACTING ON CHEMICALLY DEPENDENT WOMEN

Prior to the mid 1990s, treatment programs for chemically dependent pregnant women were fragmented and research focussed on infant and childhood outcomes in relation to perinatal chemical dependency. Since the mid 1990s, the need for specialised treatment programs has begun to be addressed and emerging research has investigated the attitudes and feelings about pregnancy of chemically dependent pregnant women (Lewis et al 1995; Murphy and Rosenbaum 1999), evaluated the outcomes of methadone treatment programs in pregnancy (Morrison et al 1995) and investigated addiction recovery in an outpatient perinatal addiction treatment program (Nardi 1999). Nonetheless, research in a worldwide context investigating the attitudes and feelings, as well as the perceived needs of chemically dependent pregnant women is scarce and virtually non-existent in Australia.

There is a need for further studies to break down health professionals' and others prejudices towards chemically dependent women. Chemically dependent pregnant women are stigmatised because of the perception of addiction held by society and the perceived reckless and

criminal nature of their actions in risking the health of their unborn child. Public opinion is often punitive and supports the belief that babies of chemically dependent pregnant women are abused and 'poisoned in the wombs of their own mothers' (Paone and Alperen 1996, p.1). Their actions are seen to run counter to the normal perception of being a caring 'good mother'. These women are often denigrated, discriminated against, condemned, ostracised and subject to intolerance, ignorance and mistrust (Lewis et al 1995; Murphy 1999; Morrison et al 1995). The opinion that chemically dependent women are unconcerned and uncaring about birth outcomes is challenged by anecdotal evidence and emerging research data (Lewis et al 1995; Ezerd 1998; Murphy 1999). Societal attitudes, while improving, are still a major factor in increasing the marginalisation and vulnerability of chemically dependent pregnant women.

Women who participate in this research by providing information about their life experiences, will do so while compromised by a uniquely vulnerable life situation, which stems from the physical, psychological and social ramifications of being a woman who, not only has a chemical dependency, but is also pregnant. Their pre existing health and social situation revolving around chemical dependence becomes exacerbated by a pregnancy that in the majority of cases is unplanned (Lewis et al 1995). Early and appropriate intervention in the form of specialist care can mean far better outcomes for mother and baby. Chasnoff (1992) reported that women who used drugs during pregnancy and received prenatal care had newborns with higher birth weights than those who used drugs and did not receive prenatal care.

A review of the physical, psychological and social factors impacting on chemically dependent pregnant women highlights the need for specialist care. In physical terms, the women have a greater propensity for eating disorders, poor nutrition, chest infections, sexually transmitted diseases and are often smokers and therefore susceptible to smoking's harmful effects. Exposure to the health issues surrounding infection with HIV, hepatitis B and hepatitis C is also a significant issue (Chasnoff 1988). The greater propensity to be involved in domestic and sexual abuse also poses a threat to the health of chemically dependent pregnant women (Murphy 1999).

Psychological issues revolve around the fear and guilt the women experience with regard to the damage their habit, lifestyle and associated health problems may be having on the health of their unborn baby (Lewis et al 1995). This is compounded by the added risk of pregnancy complications such as prematurity, ante-partum haemorrhage, restricted growth of their unborn baby, maternal infection, stillbirth and the remorse and distress they often feel in imposing what they see as 'the terrible symptoms of withdrawal', which they have experienced themselves, upon their babies (Murphy 1999). Fear also emanates from the increased risk of the involvement of child protection agencies, as well as the threat of

incarceration if any illegal practices are detected (Chavkin 1990). Loss of control over their lives, negativity and hopelessness and mistrust of health professionals and agencies may also be factors exacerbating the vulnerability of these women. If antenatal hospitalisation is required, because of physical problems, their sense of vulnerability is increased by exposure of their situation to hospital staff and other women in the unit. This issue has arisen as a significant concern for two women interviewed to date.

Social factors impacting on the women can include a lack of family support, poor housing, poverty, unemployment, exposure to violence and criminal behaviour, a history of parental substance abuse, a culture of illicit drug use in their friendship network and a chaotic lifestyle and marginalisation from mainstream society (Murphy 1999; Howell et al 1999).

All these factors illustrate the sensitivity of the research and the vulnerability of the intended participants. The 'duty of care' to protect the rights and dignity of the women, while at the same time gathering meaningful data therefore must be a primary aim (Orb et al 2001). This requires ongoing diligence in examining the ethical issues affecting the research participants. These issues, while apparently covered in current ethical clearance procedures determined by the National Health and Medical Research Council (NH&MRC) necessitate much deeper consideration and go beyond getting ethical clearance from the participating hospital and university. Ethical issues are currently being teased out, reflected upon, debated and addressed. A feminist research perspective such as described above may provide some of the answers. The first step for interviewing, accessing the women, one aspect of the proposed data collection methods, will now be addressed.

# GETTING STARTED: ACCESSING THE WOMEN

#### Who and how to approach

The first issue to arise was; who should be interviewed? Being mindful of a need to protect the rights and wellbeing of the participants, while, as a researcher, remaining conscious of the need to obtain relevant data, was and continues to be a balancing act. A decision was reached that in order to conduct valid research, invitations to participate in the study should be even handed. Nonetheless this has proven less than straightforward. In the clinic setting, some women attending the clinic can be drug affected to some degree, or be in a situation of crisis due to lack of adequate housing or finance, abuse from a partner or under threat of intervention by a child protection agency. One question the researcher debated was, 'Is it ethically and morally correct to approach women who appeared compromised?' Excluding women because they are perceived as 'too difficult' or 'too vulnerable' may diminish data collection. The most valuable data may come from these women and excluding them because of extreme difficulties in their lives, may mean the data will lack the richness a diverse group could provide. This remains a vexing dilemma and each potential participant will be assessed individually.

The next challenge to resolve was how to approach the women. Ethical guidelines stipulate that once women agree to participate they should be given adequate time to read and consider the explanation letter, before agreeing to be part of the research. The legal implications mean there is an increased requirement for vulnerable women to be fully informed and this can only occur if they are given ample time in a relaxed environment to consider participation. Taking the step to attend a specialised clinic for antenatal care is a major step for some women. Approaching them for consent at their first visit is problematic because of the considerable emotional stress they are under due to multiple demands, such as seeing members of the multidisciplinary team and having various procedures such as haematology testing and ultrasound ordered or performed. In an attempt to address this, suitable women are invited into a private area of the clinic at their second visit, usually two weeks after the first visit, and a verbal explanation of the study provided. If the woman is interested in participating, the explanation letter is given to take home and read again. Permission is obtained to telephone the woman to confirm her willingness to be interviewed and a time and place for the interview is arranged. If not amenable to being telephoned, the woman is contacted again at her next antenatal visit.

#### Specific issues relating to accessing Koori women

It became apparent, very early in planning the study, that Koori women would form part of the potential participant group. Gaining access to pregnant Koori women, who are chemically dependent, has been found to pose almost unsurmountable ethical problems within the three-year time frame available for this research.

Accessing the appropriate Aboriginal and Torres Strait Islander agency for ethics approval of any proposal involved with Aboriginal groups is compulsory under NH&MRC guidelines (1991). Written consent from the appropriate Aboriginal research ethics committee must be obtained and the protective guidelines relating to 'consultation, community involvement, ownership and publication of data' adhered to (NH&MRC guidelines 1991, pp.6-8). The research ethics committees of both institutions involved in this research stipulated this requirement. When the Koori community was approached, no local Aboriginal and Torres Strait Islander Research Ethics Committee was currently in existence and a process of referral to a number of agencies and individuals occurred.

The Koori representative, finally able to give some direction, expressed strong pejorative views and emphasised that any academic non-Koori researcher needs to have considerable experience within the Koori community in order to develop trust, and confidence in the study. Cognisance of the cultural, ethical and

methodological issues underpinning the Koori perspective, by the researcher, is vital and is of greater relevance here, because of the sensitivity of the study topic. This reflects the underpinning of the NH&MRC guidelines which point out that in the past there has been a: 'failure to appreciate that the researchers social status as determined by a community, will be a vital consideration in determining whether access to sensitive areas will be permitted' (1991, p.5).

The objections raised included the way in which academic research in the past has been exploitative and invasive, has not had any perceived benefit and findings have often not been disseminated back to the community (Holmes et al 2001). There is also a suspicion that the findings of research by non-indigenous researchers may be used against them or will not be published at all (see *Decolonizing methodologies* by Tuhiwai-Smith (1999) for a summary of these issues).

It was also noted that, even if permission was granted, there are other significant issues that would need to be taken into account in accessing Koori women for this research. Most notable is the risk of identification. Strong kinship links to 'aunts', 'mothers', 'cousins', 'brothers', 'sisters' and 'fathers' and a large family network within the community makes identification of participants very easy, especially when acceding to the moral responsibility and NH&MRC guidelines of giving study findings to the community to be reviewed before publication of them. In qualitative research the use of direct quotes and divulging even the general study location increases the potential risk.

A second issue is the sensitivity of 'women's business' or reproductive issues (see NH&MRC guidelines 1991, pp.4-5). These are considered to be extremely private and personal and something that is not read, learned about or discussed by men. The Koori ethics approval body for this research would therefore need to comprise women only and findings only disseminated to the women in the community.

A third issue in relation to informed consent is the anxiety, insecurity and fear already existing for these women based upon removal of children in the past, combined with, in some instances, poor literacy skills and different language concepts (Holmes et al 2001). To help overcome this an Aboriginal liaison officer could be co-opted to assist and explanation letters and consent forms would need to be reformatted in plain language and a peer interviewer employed to ensure that the purpose of the study and the data collection methods are clearly understood.

The researcher has been informed that obtaining clearance from a specially constituted Aboriginal Research Ethics Committee could take up to two years, which is problematic for the three year life of this study. Therefore, the unpalatable outcome is, because of the insurmountable difficulties described, and in respect of the Koori communities' wishes, Koori women will not be included in this research. So that the significant needs of

Koori women are not overlooked an approach considered is to conduct a post-doctoral research study in partnership with the Koori community after the findings of the current study have been generated. This would require consultation and collaboration with the Koori community in order to devise a unique and appropriate design and methodology to provide a culturally and ethically sensitive approach to the study topic. Having decided that it was practical to exclude Koori women from the study, the next issue to address was informed consent.

### INFORMED CONSENT

Once the woman has agreed to participate in the study, ensuring consent that is truly informed needs to be addressed. An approach that could be termed gaining 'provisional' informed consent has been and will continue to be utilised. After ensuring privacy and adequate time, participants are provided with as much information about the study as is deemed necessary. This is given in a respectful manner, while emphasising that participation is voluntary. One issue relating to honest disclosure is to fully inform participants of the legal implications in relation to mandatory reporting of child abuse (Responding to Child Abuse 2002).

The consent form, in keeping with Victorian Department of Human Services guidelines (NH&MRC 1991), states that identity will remain strictly confidential 'except as required by law'. This is an area of particular concern which relates to the *Victorian Children and Young Person's Act 1989*, (including amendments as at 1 March 2002, pp.61-80), in relation to mandatory reporting, whereby the confidentiality of participants can be breached in order to report suspected child abuse.

The legislation requires that a child, under 17 years of age, is deemed to be in need of protection if he/she has suffered or is likely to suffer physical injury, sexual abuse, emotional or psychological harm or harm to physical development or health (Section 63, c, d, e, f, p.65). If any such abuse comes to the attention of the health professionals, cited under Section 64, 1c, p.67), it must be reported. Professionals include nurses registered under the Victorian Nurses Act (1993), such as the researcher, or teachers/ lecturers under various education acts (Section 64, d, da, db). The research supervisors may fall into both categories. Therefore there is a legal obligation to report to a 'protective intervener' at the Victorian Department of Human Services if researchers deem upon reasonable grounds (Section 64, 1, and 1a, p.66) that a child is in need of protection.

The researchers are aware that a report must be made 'as soon as practicable after forming the belief' that a child is in need of protection, and after each occasion on becoming aware of further reasonable grounds for the belief (p.6). They are also aware that by reporting suspected child abuse to a protective intervener 'honest and reasonable belief' is a defence for the person

reporting (64, 1g), professional ethics are not breached (Section 64, 1h, 3, p.69), and the person making the notification is not subject to any liability if the report is made in good faith (Section 64, 1h, 3b, p.69). The *Act* also protects the identity of the person making the notification (1h, 3a, 3b, 4). However, where does this leave the study participant who has agreed to assist in the research and by so doing may reveal issues that require the researcher to breach confidentiality? This needs to be, and has been made absolutely clear to participants in the information letter and consent form.

The interviewer in this study has found the above requirement to be a very delicate one, needing honesty, tact and diplomacy. She has also been aware of a need, not to appear to label the women as potential abusers because of their chemical dependency. One strategy that has been devised is to broach the topic by making a general statement to the effect that:

Every woman participating in a study involving pregnancy or parenting needs to be aware of the legislation concerning mandatory reporting. These days there are a greater number of reportable acts relating to the safety of children in the community. Because I am a nurse and a researcher, I must tell you it is my duty, after careful consideration, to report any event of a child at risk that I am told about at any time.

This appears to be acceptable, as the women already interviewed have responded positively. At this point there has been no issues of that nature raised, however, some thought has been given to how this might be handled if and when it occurs. Given that a disclosure is made, and the role of the researcher is solely that of interviewer, the interviewer will, after consultation and in collaboration with the social worker assigned to the research participant, ensure that appropriate reporting procedures to the Victorian Department of Human Services are followed. As a matter of course, counselling and support would be provided by the social work department.

Permission now needs to be sought from the women to access their medical records. This is clearly stated on the information letter and has been incorporated into the consent process for this research, both verbally and in writing and therefore complies with the Health Privacy Principles, Schedule 1, Section 19 of the Victorian Health Records Act (2001) which became fully operational in July 2002, and the Guidelines under Section 95 of the Privacy Act (1988). A great deal of sensitive information is contained in the medical records of some chemically dependent pregnant women. Reports by social workers, medical officers and midwives, can describe illicit drug habits, psychological problems, notifications to the Victorian Department of Human Services, adherence to treatment programs, and social issues such as references to their partners, or own, criminal behaviour or incarceration. A primary focus must be to ensure that such information is only accessed with the participants'

knowledge and consent. The ethical and now legal requirement of informing participants that the researcher will be seeking to access their medical records has been addressed. To date no potential participant has withdrawn consent because of knowledge of this requirement.

# THE INTERVIEW PROCESS

Numerous ethical challenges have arisen around the interview process and the 'duty of care' to protect the well-being of the chemically dependent women participating in this study. These challenges comprise: the avoidance of exploitation, duress or obligation to participate; ensuring privacy and a non-threatening interview environment; avoidance of emotional distress or embarrassment; respecting personal privacy; provision of a non-hierarchical relationship; and, ensuring that counselling is available for participants and interviewer, if necessary, to address unforseen distress.

The avoidance of exploitation, duress or a perceived obligation for a woman to participate in the study is a primary issue. The researcher will not be providing clinical care, but will remain independent as a participant observer and interviewer only. This process will be used to avoid pressure being imposed upon the woman to consent. Gaining the confidence of the women again is a balancing act and will precede any interviewing.

Finding a suitable venue to conduct the interviews is also a challenge. Adhering to feminist tenets and ethical procedures by seeking to conduct interviews in a private, comfortable, neutral, non-threatening environment is essential in order to provide the participant with security, confidence and trust in the researcher.

The options available at present are the antenatal clinic, offices adjacent to the clinic or within the hospital, the coffee shop or the home of the participant. The antenatal clinic or offices within the hospital have the potential to alter the power dynamics in a negative way. The coffee shop, while having the advantage of establishing a more casual environment, is too exposed. While the participant's home may be an option in some cases, advice from clinic midwives suggest it may be interpreted as an invasion of privacy and an attempt to spy in order to provide information to the Victorian Department of Human Services, which may result in removal of their babies. At the same time the researcher is not equipped to deal with any problems which may arise at the time of the interview. For this reason, it is unlikely that any first interviews will be conducted in the home without a full assessment of the individual situation.

Having assessed all the options, a decision has been reached that the participant would be provided with several options as to time and place and be given the opportunity to choose one. In this way we hope to give the participant some sense of control. Initially, participants were willing to be interviewed in a consulting room or meeting room out of clinic hours when the area was quiet and conducive to privacy. The women interviewed appeared relaxed and there were no interruptions or threats of the conversations being heard by anyone else. Consequent interviews have been conducted in a park adjacent to the hospital at the suggestion of one of the participants. As the research proceeds, the choice of interview venue will be adapted according to the wishes of the women.

A further ethical challenge within the interview process emerged when considering the question, 'is it possible to fully inform potential participants when the aims and direction of the study may well change?' (Grbich 1999, p.72). Realistically, we are unable to predict the depth of information about traumatic aspects of the women's lives, which may emerge during the interview. In fact, because of the sensitivity of the issues surrounding chemical dependency during pregnancy, the interview is very likely, to appear to invade their lives. The researcher, will not set out with the intention to deceive participants regarding the purpose, direction and content of the interview. However, issues which create emotional distress and embarrassment, may be unintentionally and unexpectedly touched upon. To attempt to counteract emotional distress by providing very detailed explanations of the type of traumatic experiences, which may inadvertently be touched upon during the interview, may impede participation in the study. Therefore, a balance needs to be struck to ensure that the participants are aware of the risks of some emotional distress occurring, while being given information regarding their rights to address this. One measure in place to address this problem in relation to invasion of privacy, is outlined below.

Considerable thought has been given to the ethical question of what constitutes unreasonable invasion of privacy, during the interview process. It was aggreed that we need to be sensitive as to what might be construed as 'crossing the line' and employ a feminist research approach in the interview process to address this issue. Feminist methods require: sensitivity to the interviewer/interviewee relationship; input of study participants in both data collection and analysis; emphasis on the protection of privacy and well being of participants; and, reflexivity on the part of the researchers (Murphy 1999). Feminist interviewing techniques strive to be humane, interactive and equitable in approach. In the context of the interview, the participant provides the information and the researcher, becomes the 'tool' to collect it (Oakley 1981, p.48).

To date, establishing a non-hierarchical relationship through using a conversational, empathic approach with non-confrontational probing questions and a respect for participants' wishes not to answer or proceed with the interview if it is causing distress, has proved effective.

Finally, we also have an ethical responsibility to this vulnerable group when the interview ends to ensure the participants are not emotionally distressed or insecure about the information they have given. While it is not the role of the researcher as interviewer to provide counselling, it is essential she not only inform the participants before each interview that a counsellor independent of the research is available to provide counselling or debriefing, but also assesses the degree of need for this. As a further measure to manage emotional distress, McCarthy (1998, p.142) advocates obtaining permission of the participant to divulge a limited amount of information to a nominated care giver (staff member) in order to provide added participant support. This has not been necessary in interviews done to date. However, a follow-up phone call has been made to participants to ensure that the interview has not affected their well being in any way and has not been a negative experience.

# POWER RELATIONS IN THE OWNERSHIP OF DATA AND THE PUBLICATION OF RESULTS

A further dilemma presents itself in considering how data should be used. For example, researchers have a 'duty of care' to legitimately use data in the way it has been described to the women participating. McCarthy describes the researcher's position in relation to data as a reflection of power thus:

'The researcher is going away with your answers, analysing, coming to conclusions about you and your situation (which you may not even understand much less agree with) and then informing other people what they have discovered about you and people like you' (McCarthy 1998, p.143).

To balance this and provide a degree of ownership of the data to the women, considerable thought was given to providing the participants with transcripts of all interviews and the study findings. As have other researchers (Grbich 1999, p.72), we have had to consider the question that, if the women are given access to transcripts and the study findings and are unhappy with the substance of the transcripts, or the interpretation of the transcript, what happens then? A decision was reached, that women will be given the option of reading the original transcript, and/or a summary of research findings to date, before commencing the next interview. Any complicating factors relating to legal and psychological issues, would hopefully have been dealt with during the conduct of the interview and follow up phone call, so reading of the transcript will hopefully not pose a threat to the research in terms of withdrawal of permission to use the data.

We as feminist researchers adhere strongly to the principal that with research conducted with any vulnerable group, where participants have made a serious commitment and provided sensitive information in order to benefit others, there is a duty to publish the findings. We are also morally bound to publish results without distortion (Smith 1992) to ensure that the research fulfils its purpose in addressing a significant health issue and is disseminated to the community as intended. This is our aim, while at the same time ensuring that every effort is made to protect the identities of participants.

Finally, interviewing vulnerable groups on very sensitive topics can be a 'psychologically and emotionally wrenching experience' for the interviewer. (Burr 1996). The researcher in this study proposes to debrief, or review difficult case studies with the study supervisors, in order to deal with issues as they arise.

#### CONCLUSION

This paper has outlined some ethical issues in one study of chemically dependent pregnant women in relation to accessing participants, informed consent, confidentiality, invasion of privacy and exploitation in respect to interviewing, and how these issues might be addressed. Many more questions have been raised than answered and the issues are likely to become more complex when the needs of chemically dependent pregnant women from other ethnic backgrounds are considered in later research. However, the ethical issues, which arise when accessing and interviewing vulnerable groups on particularly sensitive topics, are problematic and at times lack definitive solutions. An attempt has been made to address the researchers' 'duty of care' as an important component of the process by adopting tenets of feminist research. Research, such as described, is necessary for improving the care provided to vulnerable chemically dependent pregnant women, probably the most stigmatised and misunderstood group in the community. However, in conducting it, reducing 'potential harm' to the study participants must be the priority and a balance needs to be established between the necessity to protect the rights of the participants, while at the same time achieving reliable and potentially beneficial findings.

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