NATIONAL STATEMENT ON ETHICAL ISSUES FOR RESEARCH INVOLVING INJECTING/ILLICIT DRUG USERS

Australian Injecting & Illicit Drug Users League (AIVL)

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Australian Injecting & Illicit Drug Users League (AIVL)
Level 2, Sydney Building
112-116 Alinga Street
Canberra ACT 2601

Postal Address:
GPO Box 1552
Canberra ACT 2601

Phone: **(02) 6279 1600**
Fax: **(02) 6279 1610**
Email: **info@aivl.org.au**

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1. INTRODUCTION

This national statement has been developed by the *Australian Injecting & Illicit Drug Users League (AIVL)* as part of a two year program of hepatitis C related policy activities. The AIVL Policy Program is funded through the HIV and Hepatitis C Section of the Commonwealth Department of Health & Ageing. The *Australian Injecting & Illicit Drug Users League (AIVL)* is the national peak organisation representing state and territory drug user organisations and issues of national significance for injecting/illicit drug users. AIVL is a peer-based organisation which means that it is run by and for injecting/illicit drug users. The membership of AIVL is made up of the state and territory drug user organisations ensuring that the organisation truly represents a national perspective on the issues that affect illicit drug users. AIVL's current member organisations are:

- *NSW – NSW Users & AIDS Association (NUAA)*
- *ACT – Canberra Alliance Harm Minimisation & Advocacy (CAHMA)*
- *VIC – Victorian Drug Users Group (VIVAIDS)*
- *TAS – Tasmanian Users Health and Support League (TUHSL)*
- *SA – South Australian Voice of Intravenous Education (SAVIVE) and the SA Users Association*
- *WA – Western Australian Substance Users Association (WASUA)*
- *NT – Territory Users Forum (TUF) and the network Against Prohibition (NAP)*
- *QLD – Drug Users Network for Education & Support (DUNES)*

The state and territory member organisations of AIVL are also peer-oriented, membership based organisations. Their members include individual injecting/illicit drug users, their families, friends and supporters of their organisational aims and objectives.

The guidelines that have informed this national statement were originally developed in 1997 by AIVL's member organisation in NSW, the *NSW Users & AIDS Association (NUAA)* for use in the NSW context. At the time NUAA developed the NSW-based guidelines, AIVL was an unfunded national network with no permanent premises or staff. As much of the research funding in the area of illicit drugs and blood borne viruses is funded nationally through the *National Health & Medical Research Council (NHMRC)*, it was decided that upon receiving funding for a program of policy activities in 2000, AIVL should adapt the NUAA guidelines into a national statement to promote further discussion and action in this area.

In developing this national statement AIVL has undertaken a comprehensive consultation process involving all major stakeholders including the AIVL member organisations, the national research centres, individual drug users, researchers, members of national advisory structures such as ANCAHRD Hepatitis C Committee and Legal Working Party, IGCAHRD, ANCD and a number of recommended experts in the areas of research, law and ethics and policy development. At the commencement of this process it was AIVL's intention to develop a set of national guidelines on ethical issues in research involving injecting/illicit drug users. Following the consultation phase however, AIVL decided that while there is a clear need for a set of ethical guidelines or standards, the development of such standards would require the combined resources and expertise of all of the major stakeholders with an interest in this issue. It is also

AIVL's belief that such a process would need to be supported and initiated by the Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD) or its equivalent in the new advisory structure and the Australian National Council on Drugs (ANCD). The involvement of ANCAHRD and the ANCD would allow for the development of a consensus document which could be promoted through the Australian Health Ethics Committee (AHEC) framework for formal recognition by the National Health & Medical Research Council (NHMRC).

As the first step in a process aimed at developing and establishing a set of national ethical standards, AIVL has developed this *National Statement on Ethical Issues for Research Involving Injecting/Illicit Drug Users.* The primary aim of this document is to promote discussion and encourage further action on ethical issues in injecting/illicit drugs research. AIVL hopes that this statement will be used to inform the debate moving forward. The statement is not about setting rules or providing checklists but rather it aims to highlight some of the key issues, provide the 'drug user perspective' on ethics in research and encourage further discussion on what constitutes ethical research in relation to injecting/illicit drug use.

Finally, AIVL would like to recognise the pioneering work undertaken by the *Injecting Drug Use Research Working Group* of the *NSW Users & AIDS Association (NUAA)* in developing the original guidelines. Although the original NUAA guidelines did not go on to be formally endorsed or recognised by research institutions, government or funding bodies within or outside NSW, they did put the issue of ethics in IDU research on the agenda. They have promoted discussion on the issues and influenced AIVL to develop a national statement to further the debate. To ensure the momentum is not lost and to support progress towards a set of recognised national ethical standards, the *AIVL National Statement on Ethical Issues for Research Involving Injecting/Illicit Drug Users* has been forwarded to the Chairs of ANCAHRD and ANCD requesting their support for a process to develop a recognised set of national ethical guidelines.

2. CONTEXT

> *"The responsibility for maintaining trust and ethical standards cannot depend solely on rules or guidelines. Trustworthiness of both research and researchers is a product of engagement between people. It involves transparent and honest dealing with values and principles, the elimination of 'difference blindness' and a subtlety of judgement required to eliminate prejudice and maintain respect and human dignity."*[1]

Illicit drug users and injecting drug users in particular, are one of the most marginalised groups in society. The reasons for this marginalisation are multi-faceted and complex and are based on a range of assumptions, perceptions and stereotypes about illicit drug users and illicit drug use as well as the impact of legal sanctions, health and financial issues. The effect of this marginalisation and stigmatisation means that many injecting/illicit drug users live with routine discrimination, extreme levels of social isolation and are frequently denied basic health and human rights. Narrow perceptions of drug users has also hampered the development of innovative methods for involving drug users as participants and partners in research and has left the community with gaps in our knowledge of illicit drug use, illicit drug using culture and illicit drug users.

Until very recently, injecting/illicit drug users were seen as passive research 'subjects' rather than as active participants and partners in the research process and outcomes. Assumptions and stereotypes about injecting/illicit drug users led to a view that drug users were incapable of being meaningful participants or equal partners in the research process. Drug users are not alone in being treated in this way in health and medical research. People with disabilities and in particular people with mental health problems, have also been assumed to be incapable of voicing valid opinion and as being unaware of their own needs and aspirations in relation to research.[2]

While there is still much work to be done in relation to collaboration and consumer participation in research involving injecting/illicit drug users, the work undertaken by drug user organisations over the past ten years has significantly contributed to changing perceptions and expectations. Despite limited resources and few opportunities for training and skills development, drug user organisations at both the local and national levels have contributed a great deal to public health research through consumer participation, collaboration and partnership. This ongoing process of consumer involvement has helped to redefine the accepted role of injecting/illicit drug users in research and encourage further debate on human rights and ethical issues as they relate to injecting/illicit drug users.

The work that has been undertaken by drug user organisations has not occurred in isolation and in many ways has been driven by both internal and external developments including:

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[1] NHMRC (2003) 'Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research', National Health and Medical Research Council, Commonwealth of Australia, Canberra, p.5.

[2] NHMRC & CHF (2001) 'Statement on Consumer and Community Participation in Health and Medical Research', National Health and Medical Research Council and Consumers' Health Forum of Australia, Commonwealth of Australia, Canberra, p. 36.

- the increasing insistence by injecting/illicit drug users that their voices be heard and that they have meaningful involvement in research about their lives including identification of research issues and feedback on research findings;
- the development of skills and knowledge in relation to research within drug user organisations which has led to demands for more involvement;
- the increasing interest and willingness of researchers and research institutions to involve injecting/illicit drug users and their representative organisations as participants and partners in all stages of the research *(Some of this 'interest' in involving drug users and drug user organisations relates more to ethical requirements and a reliance on user organisations to recruit participants than genuine interest in involving consumers but there is also a growing interest in involving drug users and their organisations amongst some researchers);*
- the development of government strategies and policies that promote partnerships between researchers and affected communities such as the national HIV and Hepatitis C strategies; and
- the increasing profile of ethical issues in research involving injecting/illicit drug users which has in part been driven by the development of the original NUAA guidelines and the AIVL consultation process for this statement.

While not exclusively focussed on ethical issues for research involving injecting/illicit drug users, the *Statement on Consumer and Community Participation in Research* developed by the NHMRC and the Consumers' Health Forum of Australia (CHF), represents a major step forward in understanding and promoting the role of consumers in health and medical research. The statement is an excellent guide for both consumers and researchers in relation to consumer participation and developing meaningful partnerships in research.

The revision of the *NHMRC Statement on Human Experimentation and Supplementary Notes (1992)* led to the issuing in 1999 of the *NHMRC National Statement on Ethical Conduct in Research Involving Humans* (usually referred to as the *National Statement*). Although the *National Statement* covers general ethical issues in health and medical research, it has also contributed to the changing environment and increased focus on ethics in research over the past few years. As the *Statement on Consumer and Community Participation in Research* recognises:

> *"The approach to research involving humans has changed and ethical consideration as outlined in the NHMRC National Statement on Ethical Conduct in Research Involving Humans now takes into account the welfare and rights of participants in research including those who may be affected by the research as well as those directly involved."*[3]

As well as the revised *NHMRC Statement on Ethics in Research Involving Humans* referred to above, other work has also been undertaken in the past few years that have had a positive influence on the involvement of consumers in health and medical research. Probably one of the most significant areas of development in relation to ethics and research in recent times has been the reworking of the *1991 Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research*. The review of

[3] NHMRC & CHF (2001) 'Statement on Consumer and Community Participation in Health and Medical Research', National Health and Medical Research Council and Consumers' Health Forum of Australia, Commonwealth of Australia, Canberra, Summary p.vii.

the *Interim Guidelines* has resulted in a new guiding document titled *"Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research"* endorsed in June 2003. *Values and Ethics* represents a major shift in the way that ethical issues are conceptualised in relation to research involving Aboriginal and Torres Strait Islander communities. Rather than a sole reliance on the quasi-legal consideration of compliance with rules, *Values and Ethics* promotes a more flexible approach based on the importance of trust, recognition and values. In explaining why this shift was necessary *Values and Ethics* states:

> *"It is possible for researchers to 'meet' rule-based requirements without engaging fully with the implications of difference and values relevant to their research. The approach advanced in these guidelines is more demanding of researchers as it seeks to move from compliance to trust."*[4]

In addition to the work outlined above, the past two years has also seen the development of training programs in the area of ethics and drug epidemiology. The UNDCP Global Assessment Programme on Drug Abuse (GAP) is currently developing a special module of its Epidemiological Toolkit on "Ethical Challenges in Drug Epidemiology: Issues, Principles and Guidelines. The aims of this module are to improve the understanding of the application of ethical principles in drug epidemiology, enhance the capacity of developing countries in data collection within ethical frameworks and to initiate an understanding of applying ethical principles in different cultural settings. As part of developing the module an expert survey of ethical challenges in drug epidemiology has also been conducted.

2.1 Why is there a need for this Statement?

While the range of activities that have been undertaken over the past five years in relation to ethics in health and medical research is indeed encouraging and has led to changes and developments in some areas, there is still a great deal of work to be done. For some years now, AIVL, the state and territory drug user organisations and some researchers have been calling for a greater degree of consultation on ethical issues relating to injecting/illicit drug use and research so that those most affected by the research will have more input into the process, impact and outcomes of such research. In a variety of forums, AIVL and its member organisations have argued for:

- more injecting/illicit drug use focused social research in particular more ethnographical research to increase the understanding of illicit drug use culture;
- more consultation with drug users and their representative organisations in setting the research agenda;
- more involvement of drug users and their representative organisations in developing and planning research projects;
- more involvement of drug users through their representative organisations in deciding where and how research funding is allocated;

[4] NHMRC (2003) 'Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research', National Health and Medical Research Council, Commonwealth of Australia, Canberra, p.5.

- more involvement of drug users and their representative organisations in carrying out research projects and in the application and impact of the findings; and
- more support for peer-driven research.

The work of drug user organisations in response to HIV/AIDS and hepatitis C, has not only highlighted the need for more appropriate and timely research concerning injecting/illicit drug users, but the peer education and community development projects such organisations have developed are also attracting attention for their social research value. Such projects have highlighted a number of important questions in regard to the way that research has been traditionally conducted amongst injecting/illicit drug users. The role of drug users as peer researchers, ethical considerations about the use of data and the affect of research findings on the lives of injecting/illicit drug users are a few of the issues that have arisen from peer-based projects.

On a national scale, AIVL and its member organisations are constantly confronted with a lack of relevant research to support and inform the ongoing development of their education and programmatic work. Drug user organisations are regularly approached to be involved in research projects after the project has been developed and funded, frequently with little or no financial reimbursement on offer and without discussion of formal recognition for involvement or input into findings and outcomes. In other cases, drug user organisations are regularly expected to participate in relevant research projects as part of their 'core business' without any recognition by researchers or funding bodies of the impact that this involvement has on the workload of the organisation.

It seems that the individual experience of drug users in research varies from one extreme to another. Some groups of drug users regularly speak of feeling 'over-researched', unclear about the objectives of the research that they are participating in, angry that they never hear back about the findings of research they participate in, have felt 'obliged' to participate in research to receive treatment and angry about inconsistent approaches to payment of participants within research projects. While other groups of drug users complain that their issues receive very little attention from researchers and that many key health, social and legal issues are either under-researched or not researched at all.

There are many reasons why injecting/illicit drug users need special consideration in relation to the ethical implications of research including;

a) many decades of legal sanctions, health and financial problems, assumptions and stereotypes have left injecting/illicit drug users in an extremely isolated and marginalised situation in society. This poor health and social status creates a range of significant barriers to conducting ethical research based on trust, respect and human dignity;

b) that past and current processes for identifying research priorities in relation to injecting/illicit drug users have not adequately taken into account the expressed needs and issues for injecting/illicit drug users or the expertise that they have to offer;

c) that there is a lack of understanding among some researchers in relation to the social and cultural context of illicit drug users lives including:

- a lack of understanding and respect for the way that drug users communicate and network with each other;
- an inadequate awareness of the barriers which prevent drug users from participating in research processes;
- a lack of appreciation of how the publication of findings and other research materials may severely compromise the confidentiality, health and safety of illicit drug users
- a failure to acknowledge the potential legal risks to the user of divulging/sharing information that discloses illicit drug use.

d) that there is a lack of appreciation of the ethical issues relevant to research involving injecting/illicit drug users which has led to:

- advice, approval and information from individuals in drug user organisations being accepted as substitute for 'actual' community consultations with injecting/illicit drug users;
- a lack of appropriate standards for obtaining consent from highly marginalised groups of illicit drug users;
- research data being used without the knowledge or permission of drug user participants;
- failure to appreciate that the researchers 'status' within the drug user networks will be a vital consideration in determining whether they will gain access to sensitive information;
- conflict between the moral, social and political positions of researchers and drug users;
- the general vulnerability of injecting/illicit drug users in terms of discrimination and exploitation within the research process
- the development of "research cynicism" amongst drug users such as drug users being unwilling to participate in research or even give false data due to their anger at the way they have been treated by researchers in the past.

It is the aim of national statement is to encourage discussion about the need for changes to the way that research involving injecting/illicit drug users, is conceptualised, used and practiced. Such changes have the potential to transform the relationship between injecting/illicit drug users and researchers. It is clearly to the advantage of research and researchers that the acquisition of knowledge and information about injecting/illicit drug use and injecting/illicit drug users occurs within the context of drug user consent, participation and involvement. Those researchers and institutions already working within ethical frameworks will understand the value of such approaches. The broad philosophy and purpose of this statement is to:-

a) encourage the development of research practice that is of a consistently high ethical standard and is beneficial to injecting/illicit drug users in Australia;

b) recognise that injecting/illicit drug users and their representative organisations have valuable experience, knowledge and skills to bring to the research process;

c) encourage researchers to formally consult with and actively engage injecting/illicit drug users and their representative organisations in all aspects of the research process;

d) propose a set of clear principles for involving and working with AIVL and its member organisations in research involving injecting/illicit drug users in Australia;

e) facilitate a shift from simply 'protecting' individual participants to actively engaging in meaningful partnership with user communities;

f) encourage researchers and research institutes to honestly review the values and principles that they bring to the research process and to assess them in relation to their ethical implications;

g) encourage researchers and research institutes to view the maintenance of trust, respect and human dignity as essential to a successful and ethical research process and outcome;

h) encourage researchers and research institutes to develop an awareness of the conditions and environmental factors that contribute to unethical behaviours and practices;

i) encourage both researchers and research participants to respect and protect each others rights and responsibilities at all stages of the research process;

j) encourage discussion about the need for a set of formally recognised ethical standards for research involving injecting/illicit drug users.

3. NATIONAL STATEMENT ON ETHICAL ISSUES FOR RESEARCH INVOLVING INJECTING/ILLICIT DRUG USERS

This statement covers a range of ethical issues in relation to planning, funding approving, conducting and implementing research from the injecting/illicit drug user perspective. To support further discussion of the specific ethical issues and concerns the statement is divided into three sections:

a) Human Research Ethics Committees (HRECs)

b) Consumer Participation in Research

c) Ethical Issues - Conducting Research

The process of gaining appropriate recognition for the issues raised in this statement will be a major focus for the AIVL Policy Program over the next twelve months. It is our aim to encourage the development of a national research ethics framework that can provide direct support and encouragement to researchers and research institutes and improve the health and well-being of injecting/illicit drug users through an effective research agenda.

3.1 Human Research Ethics Committees (HRECs)

3.1.1 Consumer Involvement in HRECs:

Any changes in the way that ethical issues are addressed within IDU research will need to be driven by the existing research infrastructure. In particular, Human Research Ethics Committees (HRECs) will have a significant role to play in bringing about a renewed emphasis on ethical practice in IDU research. Within the area of Aboriginal and Torres Strait Islander health research, HRECs have been established within Aboriginal and Torres Strait Islander controlled organisations. *Values and Ethics* describes the development of these committees in the following way;

> *"The role of HRECs is well established. Their primary function is to 'protect the welfare and the rights of participants in research'. The complexity of human involvement in research demands of HRECs the resolution of complex and often competing considerations. The composition of HRECs is intended to establish a broad scope of contribution that enables decision making inclusive of legal, spiritual, professional and lay considerations. Historically, most HRECs had few if any Aboriginal or Torres Strait Islander members and this unfortunately led to instances where clearance or monitoring of research failed to consider Aboriginal and Torres Strait Islander perspectives. This historic inability of HRECs to fulfil their function in a way that Aboriginal and Torres Strait Islander people valued led Aboriginal and Torres Strait Islanders to seek initially greater representation on existing HRECs and more recently for separate Aboriginal HRECs."*[5]

[5] NHMRC (2003) 'Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research', National Health and Medical Research Council, Commonwealth of Australia, Canberra, p. 24.

While it is important to acknowledge that the issues for Aboriginal and Torres Strait Islander health research and the health research issues for injecting/illicit drug users are very different, there are also numerous parallels that can be drawn between the two areas, particularly in relation to the process of marginalisation and its relationship to research ethics. In so far as this, there are also important lessons that can be learnt from the way that ethical issues have been addressed in Aboriginal and Torres Strait Islander health research. This is not to say that AIVL is recommending separate IDU Health Research Ethics Committees, however strategies to ensure greater expertise and understanding in relation to injecting/illicit drug use within HRECs is urgently needed.

Specifically, changes in relation to the incorporation of injecting/illicit drug user perspectives into decision making are required. Both Bastian and McNeill et al have questioned the current approach to consumer representation on HRECs. They state that lay persons on ethic committees can be outnumbered in terms of being the single 'consumer' representative on a large committee and may not be supported in their role or have accountability mechanisms back to the specific consumers who are the focus of the research proposal(s).[6] Frequently consumer representatives on HRECs are 'generalist' health consumer representatives with little or no specialist knowledge and no requirement to consult with those directly affected by the research.

Despite the fact that there is a great deal of research involving injecting/illicit drug users being considered by HRECs at any given time, AIVL and its member organisations do not currently have any mechanisms to provide input into the decision making of ethics committees. In fact, AIVL believes that the current processes and requirements of HRECs actively work against the direct involvement of injecting/illicit drug users in the research process.

Further work needs to be undertaken through the appropriate channels to determine how to support and improve existing HREC structures to actively manage ethical issues relating to injecting/illicit drug use research including:

- improved consumer consultation with injecting/illicit drug users;
- creating Illicit Drug Use sub-committees or advisory groups;
- expanding committee membership to include additional members with specialised knowledge and experience for specific categories of proposals;
- a need for guidelines to support the decision making of HRECs in relation to ethical issues in IDU research.

3.1.2 The Illegal Status of Research Data:

Research into illegal behaviours raises some complex legal and ethical issues. HRECs are increasingly concerned about the legal implications of conducting research into illegal behaviours. These concerns, while justified, must be placed in the context of a realistic appreciation of the law and its practical operation.

[6] Bastian H (1994) The Power of Sharing Knowledge, The Cochrane Collaboration, www.cochrane.org.au and McNeill et al, (1994) How Much Influence do Various Members have with Research Ethics Committees?, Cambridge Quarterly Journal of Healthcare Ethics, Special Section: Research Ethics 3, pp.522-32.

The major issue is that of access to information collected in the course of research. At the moment, data collected by researchers on illegal behaviour, including injecting/illicit drug use, do not have legally protected status to protect them from either, a search of premises by police officers or a court order to provide information and data. This raises issues in relation to the welfare of both research participants and researchers and may have implications for others involved in the research process.

Information about illegal behaviours obtained by researchers may incriminate research participants, resulting in direct harm as result of their participation in research. Researchers who fail to disclose information when called upon by a court face the possibility of punishment for contempt. For institutions, there is the prospect of civil liability for harms arising out of a breach of an employer's duty of care to the researcher and the failure to fulfil a duty of care to a third person.

Consequently, it may be no longer ethical to provide participants with absolute assurances of confidentiality even though this may 1) undermine the capacity of researchers to recruit participants; 2) threaten the validity of the research; and 3) serve to discourage the conduct of longitudinal, observation-based and ethnographic studies.[7]

However, these concerns must be placed in context. Experience suggests that the likelihood of the authorities seeking access to research material is relatively small. There is no indication, for example, that police are likely to regard material as a significant source for investigative purposes although this does depend on the focus of the research and there could be significantly more law enforcement interest in ethnographic data. The occasions when this may occur are likely to involve very serious matters e.g. the death of a participant, when researchers regardless of how the law is worded, will face ethical dilemmas about whether or not to provide information. The significant issues in this respect are ethical rather than legal ones.

Once again, further discussion of these issues will be required to investigate all of the specific legal implications at both the federal and state/territory level particularly in the context of recent federal privacy legislation changes and state/territory health record acts, prior to developing ethical standards to guide future action.

3.1.3 Criminal Law:

In the past few years increasing levels of concern have been expressed within the sector in relation to the potential criminal liability of researchers. The potential for legal action against researchers tends to have been generally overstated, in advice which is often both legally inaccurate and practically unrealistic. Criminal liability is only extended under the doctrine of complicity (e.g. to those who 'aid and abet' offences) if the complicitor is actively involved in the offence in a blameworthy manner. A researcher might fall into the category if he or she encouraged or facilitated the commission of an offence.

However, this can be clearly distinguished from the activities of a bona fide researcher: for example: observing and interviewing those involved in criminal offences is not in

[7] Fitzgerald J.L and Daroesman S., Ethical and Legal Issues When Conducting Research into Illegal Behaviours, University of Melbourne, 1996.

itself a crime. There is statutory offence of concealing a serious offence *(in the Crimes Act 1900 s.316)*. However,

> (a) serious offence means one carrying a maximum penalty of 5 years (or life) imprisonment, so excluding minor drug matters such as possession and self-administration;
> (b) a defence of 'reasonable excuse' is available; the extent of this is not defined, but would certainly be open to a researcher to claim that protection there under;
> (c) it is clear that the section is intended to narrow the previous common law offence of misprision to apply to active concealment of serious offences; there is no indication that *s.316* is likely to be applied to researchers.

These legal points need to be set in a wider context. On one side, the notional possibility of legal action, would be subject to review by senior police officers, prosecutors and other public officials who, on current experience, are not necessarily antagonistic to research, in fact, they often actively support and facilitate such research. Secondly given the relationship between drug use and public health, HRECs may also wish to consider the aggregate harm that could result from restricting research given that:

> *"If the capacity to conduct research into illegal behaviours is diminished it also diminishes the ability to develop fully-formed public strategies to reduce the harm associated with illegal behaviours."*[8]

The issues in relation to criminal liability become far more complex, however, when applied to peer-based or peer-driven research. Increasingly, drug user organisations are conducting research and evaluation as part of peer education and community development activities and the precise legal position of the individual drug users employed as peer researchers is, at best, unclear. The boundaries and distinctions that may be used in a legal case involving a recognised research institution will not necessarily apply in the case of a peer researcher. This is a particular issue if the peer researcher is a 'known drug user' or someone who is 'known' to the police.

Disproving a case of concealment of a serious offence or applying a defence of 'reasonable excuse' could be far more difficult in the case of a peer researcher. Subjective factors and prevailing negative attitudes towards drug users are likely to play a major role in deciding such cases. Drug user organisations engaged in peer-driven research projects have heard numerous claims of legal problems encountered by peer researchers including; police surveillance and harassment, confiscation of research data and participant's details, search warrants, arrest, contempt and drug charges. Not surprisingly, drug users tell each other about poor treatment from police and other service providers, which can act as a deterrent to other drug users considering participation in future research projects. This 'grey' area of criminal liability needs further discussion and resolution so that valuable peer-driven research practices can continue and develop.

[8] Fitzgerald J.L and Daroesman S., Ethical and Legal Issues When Conducting Research into Illegal Behaviours, University of Melbourne, 1996, p.4

In particular, there needs to be more discussion about strategies that can be employed by those employing peer researchers including research institutes to provide more protection to these employees. This is not an unreasonable expectation as this type of protection is currently offered to all other research staff. Unfortunately, due to the complexity of the issues, peer researchers are sometimes abandoned if there is any hint of interest from the police. This often leaves peer researchers without support and without employment. There can also be 'cultural' issues for peer researchers to deal with if their work or project comes to the attention of police. Under such circumstances, there can be an impact on the 'social standing' of the peer researcher as other users may become suspicious of their profile with the police.

The lack of legal protection for researchers, their data and hence the research participants is a very real issue and one which requires a great deal more discussion and debate amongst key stakeholders including drug user organisations, drug users, researchers, funding bodies and governments. A number of papers by researchers have been published on this and related issues, in particular, Dr. Wendy Loxley and Prof. David Hawks paper titled *Legal Protection for Injecting/Illicit Drug Use Research* offers further insight into this complex issue.[9]

AIVL believes that these complex and extremely important legal and ethical issues in relation to research involving injecting/illicit drug use must be addressed as a matter of urgency. Rather than leaving these issues to be resolved or managed by individual researchers or worse, leaving peers to fend for themselves, AIVL believes that these issues need to be addressed strategically as part of a broader process to develop national standards in this area. Such standards could be used to facilitate discussions and partnerships with law enforcement bodies and support consistent approaches to these issues.

3.1.4 Free and Informed Consent:

The issue of gaining written consent for research involving injecting/illicit drug users is both complex and difficult. The overwhelming need to protect the identity and confidentiality of participants within the area of research often leaves researchers in direct conflict with HREC guidelines on gaining written consent. While the requirement that all participants sign consent forms prior to HREC approval may be a realistic and important accountability measure for some research projects, additional options for meeting consent requirements need to be developed to accommodate projects where protecting the identity and confidentiality of participants is paramount.

For the individual drug user, more often than not, this issue of informed consent becomes far more about opportunities to gain detailed information and have their questions answered by the researcher(s), than whether or not an official form is signed. While it is undeniably important that individual drug users are given written guarantees in relation to ethical protocols. The emphasis must be on the 'quality' of the process undertaken to solicit such consent. Drug user organisations have heard reports from drug users who have given their written consent as research participants only to find out much later in the project that their consent has given the researcher powers beyond what they considered necessary for the scope of the project.

[9] Loxley & Hawks in: Fitzgerald J.L and Daroesman S., Ethical and Legal Issues When Conducting Research into Illegal Behaviours, University of Melbourne 1996.

The illegal nature of most drug use also means that the very act of signing a consent form may be considered dangerous and far too risky for many injecting/illicit drug users. It must be remembered that drug users are often asked to sign consent forms which are supposed to guarantee their confidentiality and protect their rights, only to see those rights routinely violated or ignored in the context of service delivery. Alternatively, they may have been forced, upon threat of no signature/no service, to sign degrading agreements which rather than protecting them, simply proscribe behaviour and potentially limit their ability to appeal against poor or unethical treatment in the future.

For many drug users, written consent does not necessarily mean 'free and informed consent', and it does not necessarily guarantee equitable treatment. This being the case, it is necessary for HRECs to work with researchers and drug user organisations to develop ways of ensuring that research participants in the area give their free and informed consent in a way that satisfies ethical protocols, but does not place drug users in danger.

Lisa Power a Health Advocacy Manager from the Terrance Higgins Trust in London in her letter to the BMJ on this issue argues that informed consent is fundamentally about much broader issues that a signature on a piece of paper or even a well designed consent process. She argues that free and informed consent must be about the dignity and empowerment of trial subjects and the genuine participation of patients in health research. She states that by viewing informed consent as a process of participation and respect, we can begin to look at the overall issue rather than getting caught up in whether the single act of gaining written consent constitutes informed consent.[10]

Although mostly referring to clinical trials, Power also outlines some of the changes in thinking and action that will be needed to transform the issue of informed consent from one that is seen as a burden or a hassle to something that has the potential to improve the outcomes of research for both researchers and participants…

> *"To improve the practice of obtaining informed consent wherever possible there must be a number of changes in attitudes. There needs to be a greater emphasis in doctors' education on interpersonal and communication skills, and a greater willingness on the part of some trial investigators to involve nursing staff in communicating with trial volunteers; doctors are not the only people with a voice and a brain. Secondly, there needs to be an understanding that giving patients or potential patients some say in the design and approval of trials is a positive process and not just a hoop to jump through. This involvement can stretch from trial design to writing information sheets and sitting on ethics committees. Thirdly, the onus should be clearly on those designing trials to show, as part of their basic data, their process for subject consent and uptake, rather than on others to challenge them in retrospect."*[11]

The issue of informed consent within research has been the subject of a great deal of debate and discussion both within Australia and internationally over the past few years. In particular there has been work developing in Australia specifically in relation to IDU

[10] Power L (1998) Trial subjects must be fully involved in design and approval of trials, BMJ, 316:1000-01.
[11] As above

research that is seeking to shift practice away from an exclusive reliance on evidence of written consent to a more progressive and comprehensive approach to gaining free and informed consent. Issues such as confidentiality, the potential dangers associated with disclosing an illegal behaviour, the ethical issues associated with gaining informed consent from highly intoxicated people and/or drug users with mental health problems, have all lead to the view that current requirements need to be revised in favour of a more comprehensive and flexible approach.

While AIVL is supportive of a thorough review of current HREC requirements for informed consent to take on board some of the specific needs and issues involved in IDU research, we are also very concerned that such a process does not lead to an erosion of ethical standards for informed consent with injecting/illicit drug users. At the same time however, AIVL and its member organisations are aware that simply having rules in relation to informed consent do not necessarily guarantee that those rules will be implemented in good faith. AIVL also recognises that there are many real restrictions on researchers and research institutes but these limitations cannot be allowed to affect their ability to gain free and informed consent from participants.

Some of the key aspects of a more flexible yet comprehensive approach to gaining free and informed consent with drug users might be:

- More active involvement of research participants and peer-based drug user organisations in all stages of the research process to significantly aid understanding of the aims, processes and outcomes of the research;
- Supporting peer-based drug user organisations to develop and disseminate information about the research that is accessible, credible and trusted by participants. This information must be disseminated with sufficient lead time to allow potential participants to absorb the information and ask questions. The use of peer networks would also support the distribution and credibility of the information;
- Supporting peer-based drug user organisations to run information sessions for potential participants in an environment that is comfortable and safe for drug users;
- Developing other forms of recording consent that may feel safer than written consent for participants including tape recording verbal consent;
- Developing the communication skills of researchers to support better two-way dialogue between research and participant;
- Engaging more peer researchers in all stages of the research process including in gaining informed consent with participants. This may involve peer researchers working in small groups of drug users to support better exchange of information and discussion of issues;
- Involving potential participants in more qualitative peer-based processes over a period of time will also address issues such as gaining consent from people who are highly intoxicated, as this is a 'natural' aspect of peer interaction rather than the person being viewed as 'dangerous' or 'out of control'.

AIVL believes that peers are the key to ensuring more ethical standards in relation to informed consent in IDU research. By and large, drug users are more comfortable with other drug users and, other users often know when someone is uncomfortable or doesn't understand the process. Researchers need to work in partnership with drug

users to resolve the current concerns with the consent process. Developing more ethical and effective consent processes will also depend on researchers gaining a better understanding of both the real and perceived concerns that many drug users have in relation to health research. For example, one of the major concerns that some drug users have is that they will be denied treatment or services if they do not consent to participate in certain research. Such concerns need to be taken seriously, whether they are perception or reality and addressed in a way that instils confidence in drug users.

There is a great deal of future work that needs to be done by HRECs in relation to the issue of free and informed consent in the context of research involving injecting/illicit drug users. In the final analysis, AIVL does not believe that this issue needs to be overly difficult or complex to resolve. Ultimately, free and informed consent can be achieved in IDU research if there is sufficient commitment to do so. There needs to be commitment to true partnership and collaboration with injecting/illicit drug users and commitment to the human rights and dignity of participants. Doyal summarises it in the following way…

> *"I still disagree with those authors who argue that it is not necessary to obtain informed consent if this will lead to the methodological compromise, or possible cancellation, of potentially beneficial studies involving clinical interventions that carry minimal risks. What these correspondents either fail to recognise or to take seriously is that to fail to respect the autonomy of competent people is to inflict harm on them that is just as morally unacceptable as direct physical or mental harm. To do so rejects the letter and spirit of the Helsinki Declaration—the "interests of the subject must always prevail over the interest of science or society." Simply to assert that the declaration is wrong in this regard is to embrace the dogma of scientific progress at any price. When human autonomy and dignity are at stake the cost of such progress is too high."*[12]

3.1.5 Peer-Driven Research and HRECs:

With the increase in peer-driven research by drug user organisations there are a range of emerging issues in relation to ethical standards and ethics approval that need to be addressed. Given that peer-driven research by its nature is largely conducted by peer-based non-government organisations with no direct relationships with HRECs, it has never been entirely clear on how such organisations should proceed in relation to ethics clearance. Unfortunately, rather than there being any move to resolve this issue, those undertaking peer-driven research have simply found themselves isolated in terms of the process and ignored in terms of the important research they are doing.

Recently, AIVL initiated the organisation's first major peer-driven research project for which the organisation was keen to seek formal ethics approval. AIVL believed that despite the organisation not being formally linked to a specific HREC, it was important for AIVL to demonstrate a capacity and willingness to meet appropriate ethical standards. It was felt that this would not only demonstrate national leadership by

[12] Doyal L (1998) Ethical debate: Informed Consent – a response to recent correspondence, BMJ, 316:1000-01.

providing a best practice model for other peer-driven research projects to follow, but it would also ensure that peer-driven research met the same rigorous ethical standards expected of mainstream research. Unfortunately AIVL experienced a range of difficulties and barriers within the existing HREC structure and process including:

- A general lack of clarity about requirements for NGOs in relation to ethics approval;
- Difficulties in accessing information about the process – who we had to talk to, information about the application process and submission dates, how much information we had to submit, information about the decision making process, overly secretive processes in relation to when the HREC was meeting, etc;
- It was an extremely onerous process that was unrealistic for a small NGO with limited resources;
- The application required sign-off from a very senior level in the health bureaucracy which was simply unrealistic for a peer-based drug user organisation initiating its first major peer-driven research project;
- An existing ethics approval process that is based on demonstrating a long-track record in research or demonstrating the involvement of individual researchers with such a record – this served to undermine the peer-driven nature of the proposal;
- Lack of expertise on the HREC in relation to peer-driven research involving injecting/illicit drug users – this resulted in little or no understanding of AIVL or the organisation's expertise in peer-based approaches;
- Our experience as drug users was viewed more as a 'disadvantage' rather than an essential requirement for a peer-driven project – highlighting the need to address the issue of specialist advisory committees to support the work of the HRECs;
- No recognition that peer-driven research projects may require a more flexible approach to ethics approval that recognises limited resources and the importance of peer control of all stages of the project despite having limited research experience;
- Impact of the political environment – HRECs need to be aware that the politics surrounding illicit drug use can have a negative effect on whether a drug user organisation can gain support at a departmental level for important research projects;
- A lack of recognition of the training and skills development needs of peer-based NGOs – AIVL had no previous experience with gaining ethics approval but there seemed to be no support available to assist us in developing the required skills other than handing over control of the project to non-peers;

The implications of not gaining ethics approval are significant for drug user organisations particularly when they are attempting to build their research skills and capacity. The inability to gain clearance can limit the expertise that such organisations can attract to their projects as other researchers are often unable to be involved in projects without ethics approval. This not only has a negative impact on the development of partnerships between the community and research institutes but also limits the opportunity for skills and information sharing. Of course, the implications of not gaining ethics approval also mean that drug user organisations are forced to risk legal liability and are unable to publish the results of the research in certain professional journals.

Although AIVL does not believe that it would be necessarily appropriate to require peer-driven research initiatives to follow existing ethics approval guidelines due to many of the problems outlined above, we do support the development of a flexible and appropriate ethics clearance process for peer-driven proposals. This process would need to take into account the limited resources available to peer-based NGOs, as well as recognise the right of peers to conduct research amongst their communities on the issues that affect them in ways that are appropriate for them. Given that research conducted *by* drug using peers raises very different ethical issues to research conduct *on* or *with* drug users, consideration would need to be given to how this distinction is recognised within any peer-based ethics process.

As part of any process to develop a set of national ethical standards specifically for IDU research, there will need to be a more detailed discussion about the management of peer-driven proposals. The peer-based drug user organisations are keen to follow appropriate ethical standards for peer-based projects in relation to any research projects they conduct. Their main concern is to avoid the current situation where such organisations are, at best disadvantaged and at worst, excluded from the ethics approval process.

3.1.6 Multi-Site Research Projects:

Decreases in the overall amounts of funding that are available for research projects has increased the incidence of multi-institutional research proposals before HRECs for approval. This situation has created difficulties for researchers who are required to seek ethics approval from numerous HRECs for a single multi-institutional research project. Differences in the process, timelines and approval protocols between HRECs are causing major delays for specific projects and a great deal of frustration for the researchers involved.

The complex nature of a great deal of research involving injecting/illicit drug users has lead to an increase in the frequency of collaborative multi-site projects. Additionally, the ongoing need for comparative data in the development of state-wide education and prevention campaigns has made multi-site research a public health necessity. The lack of guidelines and protocols for the development and approval of multi-site projects is also providing a significant disincentive for researchers who might otherwise consider a collaborative partnerships project with the community sector.

A specific set of ethics approval protocols for HRECs handling multi-site projects needs to be developed and implemented, as a matter of urgency.

3.2 Consumer Participation in Research

> *"Research is a powerful tool, and those who control health and medical research have considerable influence over the health care system and a profound effect on the lives of all health consumers and their families. Those who are to benefit (or suffer) from the decisions made by researchers, policy makers and health care administrators should be an integral part of the decision-making process."* [13]

[13] NHMRC & CHF (2001) 'Statement on Consumer and Community Participation in Health and Medical

Definition of Consumers:
In the context of this statement, the term "consumer" should be read to mean individual injecting/illicit drug users or peer-based drug user organisations representing injecting/illicit drug users. The term "consumer representation" is used to mean the participation of the injecting/illicit drug user community, through nominated representatives, in processes, forums or committees where policies, interventions or services that affect users are planned, discussed, researched, determined, co-ordinated or evaluated. Finally, the term "consumer organisation" is used in this document to mean AIVL and/or the state/territory peer-based drug user organisations. All of these definitions are consistent with existing AIVL policy on consumer participation, consumer definitions used in other parts of the health sector and definitions used by the NHMRC, Consumer Health Forum of Australia and the National Health Service (NHS) in the United Kingdom in the health research context.

3.2.1 Consumer Participation and Consultation:

The role of drug user organisations and injecting/illicit drug users in the designing, development and conducting of relevant research needs to be formally recognised by researchers, research institutes and funding bodies as a matter of urgency. AIVL, its member organisations and individual drug users must given the opportunity to have a say in the direction of research involving injecting/illicit drug users. Further, the role of drug users as peer researchers needs to be recognised and encouraged through the development of formal systems and processes to support their involvement.

There are many obvious benefits to addressing the issue of community involvement and control as it relates to this area of research, particularly in terms of access to drug users and community support for research findings. Equally, there are also numerous negative consequences that could result from researchers choosing to ignore the issue of drug user involvement and participation. One of these main consequences is the potential effect on future research projects if drug users become alienated from research processes and agendas.

There are essentially two key reasons why consumers should be supported to participate in health and medical research these are:

1. Their right to do so;
2. The contribution that they can make.

AIVL believes that consumers have a right to participate in research that has an effect on their lives and be supported to be active partners in all stages of the research process. As current drug users, consumers and consumer representatives have access to unique information, experiences and relationships that can have real benefits for research. AIVL also recognises the importance of balancing the rights and responsibilities of both consumers and researchers, including engaging in processes that are respectful of the perspectives, positions and needs of both groups. This 'shared

Research', National Health and Medical Research Council and Consumers' Health Forum of Australia, Commonwealth of Australia, Canberra, p. 1.

responsibility" between consumers and researchers should fundamentally be about ensuring the ethics and value of the research.[14]

In recognising the rights of consumers to have a say in research that affects them – what is researched, how the research is conducted and how the outcomes are used, we also need to acknowledge that researchers have a right and need to use their skills and investigative drive to research issues that need to be explored. Essentially we need to strike a balance and find ways to promote and protect the rights and needs of both researchers and consumers. AIVL believes that the development of partnerships based on trust and understanding are the key to finding the right balance.

a) What is Consumer Participation and Consultation in Research?

The Draft Consultation Paper: Guidelines on Research Ethics Regarding Aboriginal and Torres Strait Islander Cultural, Social, Intellectual and Spiritual Property developed by the *Centre for Aboriginal and Torres Strait Islander Participation, Research and Development* describes the process of consultation in the following way:

> *"Consultation must be regarded as the process by which researchers secure the right to participate in a particular knowledge domain, for a specific set of negotiated outcomes that they may use only with the agreement of the owners and managers of the knowledge domain."*
> **(Draft Consultation Paper: Guidelines on Research Ethics Regarding Aboriginal and Torres Strait Islander Cultural, Social, Intellectual and Spiritual Property, Centre for Aboriginal and Torres Strait Islander Participation, Research and Development, James Cook University, April 1995.)**

It is within the context of partnership, ownership and self-determination that we need to develop protocols for research based consultation with injecting/illicit drug users. On some occasions, consultation associated with injecting/illicit drug use research projects is little more than the act of a researcher or a group of researchers seeking agreement or permission to do something 'to' or 'for' injecting/illicit drug users. The aim is the collection of data, not the development of a partnership that can increase the potential for information sharing and greatly enhance the quality of the project.

Consultation should be a process that allows the people being consulted to say "Yes" or "No" without punitive outcomes, prejudicial treatment or conditions being applied. Specifically, we need to develop processes that ensure that there is no pressure on the participant to be involved in a research project simply to get access to services, information, treatment, support, etc. To facilitate the development of such processes, we need further discussion about the reasons why injecting/illicit drug users participate in research, the needs of those participants and whether participation in research is the best way to meet those needs. The key questions of who will benefit from the research and in what ways, is frequently overlooked in research involving injecting/illicit drug users.

c) Levels of Consumer Participation and Consultation:

[14] NHMRC & CHF (2001) 'Statement on Consumer and Community Participation in Health and Medical Research', National Health and Medical Research Council and Consumers' Health Forum of Australia, Commonwealth of Australia, Canberra, p.1.

Any consideration and discussion of what constitutes meaningful "consumer participation" needs to take account the different levels and types of consumer participation in current research. AIVL believes that the framework for understanding levels of consumer participation outlined in the *Statement on Consumer and Community Participation in Research* is a good starting point for discussions in relation to IDU research.

Bastian describes participation as an active process where participants have at least the potential for significant influence. Real participation implies sharing of decision-making power. Drawing on previous work by others (Arnstein 1969; Birchman et al 1989) she summaries the levels of consumer participation as follows:

1. **None** – with this approach consumers' perspectives and concerns are not specifically addressed. The consumer is a "passive subject" whose only role is to comply with requests from the researcher. This approach is often used in clinical research with a traditional patient/doctor approach. Data may be used without the subject's knowledge or permission and subjects are often not really aware that they are involved in research. Consumers are not involved in the research planning, development or implementation and consumers are not informed of the outcomes of the research. In this model, there is no consumer participation as the researcher is considered the 'expert'. Although some research has progressed beyond this approach, there is still plenty of research involving injecting/illicit drug users conducted with no consumer participation.

2. **Manipulation** – in this approach a participant might be given a certain level of information about the project to encourage them to be involved but they are only given partial information and they are not provided with ongoing information during and after the research. For example a consumer organisation or representative might be invited to participate in a research steering committee due to their knowledge of the target group and they might assist the researchers to develop the project funding proposal or help to recruit participants. Alternatively, this approach might involve a consumer representative being invited to join a reference group or steering committee but they are treated as 'token' representatives and their views and input is either not taken particularly seriously or is actively discouraged. The consumer involvement usually ends when the project is funded and the research commences. Unfortunately, a great deal of the research experience for AIVL and its member organisations would sit in this category of consumer participation despite the fact that such low level of involvement and manipulation are in fact inconsistent with the policies of the Commonwealth Department of Health and Ageing which support the "active involvement of consumers at all levels of the development, implementation and evaluation of health strategies and programs".[15]

3. **Restricted Scope** – involves experts advocating their perception of the consumer's views and the consultation with consumers can sometimes be 'tokenistic'. In this approach to participation the consumer might be recommended to participate in a clinical trial by a health professional but the consumer is not given adequate information to really think about the potential

[15] Consumer Focus Collaboration (2001), The Evidence Supporting Consumer Participation in Health, AGPS.

costs and benefits before making a decision to participate. The health professional may not be fully aware of the influence that they have over the consumer particularly if there is an ongoing medical/health service relationship involved. In the case of consumers who are injecting drug users, they can be concerned that they will suffer if they don't participate or alternatively, they think that they 'should' participate as an act of support for the service/program.

This approach may also involve limited consultation with consumers such as consultation on the development of a research proposal or methodology but the researchers then 'second guessing' the consumer view and excluding consumers from further decisions about the research implementation, data analysis and outcomes, dissemination, etc. This approach can often involve the researcher believing that they are 'acting in the best interests' of consumers. The problem with this restricted participation, is that in 'acting for' consumers there is a risk that the findings of the research will not represent the real or actual needs and concerns of consumers but a perception of those needs. Depending on the nature of the research, this could affect the quality and usefulness of the evidence significantly. It can also mean that despite the existence of research, consumers may not have access to the information that they really need to make choices about treatments, services, health issues, the benefits and costs of a particular treatment, etc.

Although current NHMRC ethical requirements in research involving humans do address some of the issues with restricted participation in clinical trials, they do not address this issue more broadly in research. While many areas of research involving injecting/illicit drug users have been moving towards greater levels of consumer participation, these developments have been slow and gradual. The majority of AIVL and drug user organisation involvement in research remains within a restricted participation approach with researchers are still 'acting on behalf' of consumers after minimal levels of consultation.

4. **Open Involvement** – this approach involves a greater level of consumer participation with consumer representatives on research steering committees, possible support so that the consumer representatives can consult with and be accountable to the consumers they represent and consumer representatives participating in other parts of the research process. The limitations with this approach are that the consumer representatives are usually brought on after the research has been funded and therefore have no say in prioritising the research topic and focus in the first place or in the development of the proposal and methodology. While the open involvement approach is far preferable to the other approaches described above in terms of consumer participation, it still risks research being prioritised that does not met the real needs and issues for consumers. The lack of consultation with consumers in developing the research proposal also risks research being undertaken in a way that excludes or discourages certain consumers from participating. Both of these issues could potentially have a major impact on the quality, effectiveness and relevance of the evidence produced from the research.

5. **Wider Participation –** with this approach consumer representatives represent the consumer view at all stages of the research process. In addition, consumers

are widely consulted and encouraged to participate and a variety of strategies are used to ensure that consumers have adequate access to information and that consumer experiences inform the research outcomes. This approach ensures that consumer representatives are involved in all decision making, regardless of whether the researcher believes that they already 'know' the consumer view. This approach also acknowledges consumer expertise and the importance of having a consumer representative to focus exclusively on consumer issues in each discussion and decision. Wider participation can only operate effectively with adequate time and resources to support strong community consultation.

There also needs to be recognition that consumer representatives often carry an enormous weight of expectation and responsibility. Sometimes, depending on the research, consumer representatives can carry the hopes and fears of an entire community. They often have direct and personal links to the research and the process can be a highly emotional experience for them. For this reason, the wider participation approach also requires adequate mechanisms and resources to support consumer representatives in their roles including feedback loops with their communities so that they are not isolated remuneration for their work, debriefing opportunities and other support strategies.

Wider participation also includes peer-driven research or research that is undertaken from the consumer perspective by consumers arising out of consumer identified needs. The value of consumer or peer-driven research cannot be underestimated particularly in relation to highly marginalised and disempowered communities such as injecting/illicit drug users. This type of research helps to build up a more complete picture of the consumer perspective and identify issues that would otherwise remain undocumented and under-researched. Peer-driven research can often bring a different perspective to our understanding of injecting/illicit drug use issues and have the effect of putting previously unrecognised or misunderstood issues on the agenda.

One of the major issues that need to be considered in the wider participation approach is the limited resources of most consumer organisations. In particular, drug user organisations have extremely limited resources and most are not funded adequately to participate in all of the research projects that they are expected to participate in or invited to participate in. Supporting the wider participation approach then includes providing drug user organisations with adequate notice and information about the project, building adequate resources to support consumer participation into the project budget and respecting the right of drug user organisations to set their own priorities in terms of their level of participation in research. Injecting/illicit drug users are researched a great deal and small drug user organisations can easily experience 'research fatigue'. The wider participation approach aims to work with consumer organisations to identify the appropriate level of participation for the particular project; from a letter of support through to contributing to the design, direction, conduct and dissemination of findings, depending on the needs and issues for consumers. The key is that consumers make the decisions for themselves about their level of

participation in consultation with the researcher, rather than the researcher or research institute making decisions about consumer participation in isolation.[16]

3.2.3 Principles for Participation and Involvement:

To further and support consumer participation and involvement in research, AIVL suggests the following principles for action;

Collaboration and Partnership – that there is a need for flexible collaboration processes between researchers and consumer organisations in relation to research priority setting, development and design of research proposals, conducting research projects and disseminating findings. Such collaboration needs to include the development of a variety of formal and more informal working partnerships between research institutes and consumer organisations, including but not limited to consultancies, sub-contracting consumer organisations to carry out specific components of research projects, full partnerships based projects, etc.

Consumer Participation – that consumers will be supported to participate in all aspects of the research process including setting research priorities, developing proposals and methodologies, conducting research, disseminating the findings and assessing the research outcomes for future action.

Consumer Consultation – that researchers will consult with consumer organisations in the development of research proposals to identify issues and concerns, to discuss the potential costs and benefits of the proposed research for consumers and to check the appropriateness of the planned approach from the consumer perspective;

Supporting Consumer Research - that consumer/peer-driven research is recognised as an important and valuable component of consumer participation in research and that the development of consumer/peer-driven research projects is actively supported by researchers and research institutes.

Supporting Consumer Researchers – that consumer/peer researchers will be used wherever possible in research projects.

Recognition of Consumer Expertise - that the expertise and credibility of consumers and consumer organisations be recognised and treated in the same way as the expertise of other key stakeholders, that is, it is respected, properly remunerated, taken seriously, listen to and acknowledged.

Resourcing to Support Consumer Participation – that adequate resources to support the full and ongoing participation of consumers and consumer organisations in research is planned into project budgets including sitting fees and other expenses for consumer representatives, funding for all aspects of participation for consumer organisations, payment for consumer focus groups

[16] The "levels of participation" approach was drawn from NHMRC & CHF (2001) 'Statement on Consumer and Community Participation in Health and Medical Research', National Health and Medical Research Council and Consumers' Health Forum of Australia, Commonwealth of Australia, Canberra, pp.3-8.

and research participants, funding for the development and dissemination of information for consumers, etc.

Communicating with Consumers – that researchers need to develop their skills in relation to engaging and working with consumers and consumer representatives and ensure that they are well informed in relation to the issues and needs of consumers to support more meaningful consultation and partnerships;.

Respecting Consumer Rights – that researchers will respect the fact that consumers have a *right* but not an *obligation* to participate in research that affects or involves them.

Informing Consumers – that researchers will provide information in forms that are accessible to all consumers and are able to be readily understood by them. This information should include details of how they will be consulted and involved in the process, the purpose of the research, how the research will be conducted, how data will be collected, analysed, managed and stored, how reports will be drafted, published and disseminated and how the research outcomes will be used. It should also list any potential costs to consumers or consumer organisations as well as potential benefits. Also, sufficient time needs to be allowed for consumers and consumer organisations to assimilate and respond to the information provided. Consumers should also be provided with information that informs them that their consent may be withdrawn at any time.

Training for Consumers - that appropriate training and development in the skills necessary for them to carry out their role effectively should be made available to any consumers involved in research projects including but not limited to consumer representatives, consumer organisations, peer recruiters, peer researchers, etc;

3.3 Ethical Issues – Conducting Research

The aim of this part of the statement is to provide some key principles to inform the future development of a set of formal national ethical standards. While the previous sections on HRECs and consumer participation have focussed on broad discussion of some of the issues that underpin the research process, this final section is more targeted and puts forward some proposed ethical standards for conducting research. It should be noted that these proposed standards represent ethical issues and rights from the consumer perspective. AIVL acknowledges that there may be other issues and perspectives to bring to the process of developing a final set of ethical standards but has put forward these suggestions as a starting point and as a basis for further discussion. In the absence of a set of formal ethical standards, however, AIVL also believes that these proposed standards could provide researchers with a guide for action. Rather than viewing these proposed standards as a 'checklist' to be worked through regardless of the circumstances, AIVL would encourage researchers to view them as 'prompts' or as suggestions to guide thinking and encourage critical analysis of values, judgements and actions in relation to consumers. The proposed standards have

been divided into four sections with each sub-section focusing on a specific area or stage in the research process.

3.3.1 Planning and Conducting Research:

Researchers are in a position of privilege and trust and should conduct themselves in a way that recognises this status. AIVL believes that the way that researchers approach the initial planning and development phase of any research project sets the scene for how and whether consumers will be involved in the rest of the project. Also, engaging consumers and consumer organisations in the research process must be about more than simply meeting funding and HREC requirements. The process of encouraging and supporting consumer participation and involvement in the planning and conducting of research must be based on trust, respect and a genuine commitment to high quality, relevant and ethical research.

In the spirit of encouraging further discussion and action towards a set of national ethical standards, AIVL has developed the following suggestions in relation to the responsibilities and obligations of researchers during the planning and conducting of research…

a) ensuring that consumers and consumer organisations have been consulted and involved in the planning, development and design of the proposed research including the development of methodologies;

b) ensuring that consumers understand all the possible costs and benefits of the proposed research;

c) ensuring that issues and concerns for consumers in relation to the proposed project are identified, taken seriously, recorded and addressed wherever possible;

d) ensuring that the final project proposal includes methods that consumer's value and outcomes that benefit consumers;

e) ensuring that consumer's rights have been identified and addressed in the research proposal and that during the research consumers are aware of their rights and avenues for complaint;

f) ensuring that funding to adequately support the ongoing participation and involvement of consumers and consumer organisations has been included in the proposed project budget;

g) ensuring that the training needs of consumers and consumer organisations have been planned into the research proposal;

h) ensuring that strategies to support the effective dissemination of research results to consumers and consumer organisations have been included in the research proposal;

i) ensuring that all consumers involved in the research are well informed of all stages of the research project and are clear on the implications of each aspect

of the project including purpose and aims of the project, methods, risks, inconveniences, discomforts, how the research will be conducted, security and confidentiality issues, uses of the research, etc. Specifically, if a project involves clinical trials or similar, all participants will be informed in detail about how clinical trials work, why this approach is being used in this project and of the short and long term implications for their health and well-being;

j) ensuring that consumers will not be disadvantaged, suffer any adverse health consequences or jeopardise their health and wellbeing due to their participation in the research;

k) that consumers should not be asked to participate in research trials or projects that could be potentially harmful for the participants;

l) that consumers should not be asked to participate in research trials or projects that could potentially expose them to a sub-standard product or service;

m) ensuring that consumers and consumer organisations are involved in the development of research instruments including commenting on draft surveys and focus testing questionnaires;

n) ensuring that consumers and consumer organisations are properly informed and consulted if research questions for other research projects or evaluations are to be included or 'piggy-backed' into the another survey/questionnaire. In this case, there should be clear benefits for consumers in the inclusion of the extra questions and participants must give their free and informed consent;

o) ensuring that sufficient time is allocated for the consumers and consumer organisations involved in the research to assimilate and respond to the information in relation to the project and the potential implications for their lives. (The amount of time needed should be negotiated with those involved so that the needs of both the participant and researcher can be accommodated.);

p) ensuring that the researcher(s) are fully trained to be able to respond to participants questions and correct any misinformation on the subject matter and related issues;

q) ensuring that appropriate information materials and support is available for participants following the administration of questionnaires to address any issues that may have arisen during the interview;

r) that all consumers and consumer organisations are advised at regular intervals, of the progress of the research project and informed ahead of time if there needs to be changes to the project;

s) explain the potential uses to which any film, photographs, sketches, audio and video recordings will be put at the outset of the project. The conditions of access to and use of, this data should be negotiated through a process of free and informed consent. This should specifically include any intention to use

such images and recordings at public events such as conferences. It should also include informing consumers of the need to remove or cover any identifying jewellery, piercings, tattoos, etc before being photographed, filmed, videoed, etc;

t) ensure wherever possible that consumer/peer researchers are used in the project;

u) ensure that all consumer representatives and consumer organisations are paid for their time and reimbursed for expenses including but not limited to sitting fees, costs of consulting and running focus groups, personnel, out of pocket expenses, administrative costs, etc.

v) build into the research methodology a debriefing process following participant interviews (particularly when the participant has been asked to provide very personal or potentially emotive information);

w) ensure that pre and post test counselling is offered when diagnostic blood tests or other similar diagnostic procedures are part of the research methodology.

x) ensure that all consumers involved as participants in research projects are reimbursed to recognise the expertise and information that they have provided and to cover any out-of-pocket expenses. Researchers should also ensure that such payments are provided directly to participants rather than participants being paid 'in-kind' through food, vouchers, etc. The decision on whether participants received the payment should not be left up to services assisting the research project but rather should be the direct responsibility of the researcher(s);

y) ensure that the research structure, including the sampling frame, do not directly or indirectly prevent certain injecting/illicit drug users being targeted by the research and from participating in the research project. Special attention should also be given to ensure that the needs and issues of groups such as youth, women, NESB and Aboriginal & Torres Strait Islander drug users are addressed appropriately and adequately.

3.3.2 Storing, Managing, Analysing and Reporting of Data:

Too often, consumers and consumer organisations are excluded from this stage of the research process. AIVL believes that this is a fundamental error as many of the most useful and significant research projects in the blood borne viruses area have been those where consumers and consumer organisations have been key players in the data analysis and development of the final report. As the research findings have direct implications for the lives of consumers, they have a major investment in ensuring that the research findings are relevant, appropriate and will not have a negative impact on consumer's lives. Consumers can also assist researchers to understand complex rituals and behaviours and ensure that sensitive and important issues are not taken out of context and are handled in a respectful manner. In short, consumers can bring a valuable 'reality check' to this part of the research process.

In the spirit of encouraging further discussion and action towards a set of national ethical standards, AIVL has developed the following suggestions in relation to the responsibilities and obligations of researchers during the analysing, managing, storing and reporting of research data…

a) ensuring that consumer representatives are actively involved in the analysing of research data including identifying key themes, reality testing the data, assisting with drawing realistic and practical conclusions, ensuring that information is not taken out of context, suggesting consumer friendly ways of presenting the data, etc;

b) ensuring that consumer representatives are actively involved in the development and editing of the research report and any other information or materials produced as a consequence of the research process;

c) ensuring that research findings do not inadvertently trivialise, over-pathologise, demonise or sensationalise aspects of injecting/illicit drug use or the lives of injecting/illicit drug users;

d) ensuring that research reports remain focussed on improving the health outcomes for consumers;

e) that wherever possible, following completion of the data collection and analysis, and before any publication or presentation of this data, a summary of the findings should be made available to consumers and consumer organisations involved in the research;

f) ensuring that results are not presented in a way that could be misleading for consumers or cause distress, increased discrimination and stigma or anger towards consumers;

g) ensuring that a process for the return, destruction or secure storage of all identifiable material and data on the completion of the research, is negotiated prior to the commencement of the project;

h) ensure that results will not be published in a form that allows for the identification of individual participants including the potential identification of individuals from tattoos, jewellery, etc;

i) ensure that proper acknowledgement will be given to consumers and consumer organisations who have taken part in the research. (of course, for the sake of confidentiality naming of individuals particularly peer researchers and acknowledging participation may not be desirable, however, this should be negotiated with the individuals concerned at the outset of the project.);

j) that wherever practicable, consumer/peer researchers will also be involved in the preparation of publications and will be acknowledged. Publication acknowledgements should be in line with the NHMRC Statement on Scientific Practice;

3.3.3 Dissemination of Research Findings:

Unfortunately, the lack of involvement of consumers in the dissemination of research findings has resulted in many consumers having participated in enormous amounts of research but having little or no knowledge of what those research projects have found. This has created a sense of frustration and alienation amongst consumers and consumer organisations and only serves to reinforce views amongst consumers that their involvement in a great deal of research is at best tokenistic, and at worst exploitation. There is an urgent need to create a better balance between the pressure on researchers to publish their research findings in professional, peer-reviewed journals on the one hand, and the need for consumers to gain access to research findings that have a direct bearing on their lives and heath, on the other. AIVL believes that this balance can be achieved through the implementation of ethical standards that create incentives for researchers to engage with consumers in the dissemination of research findings. While AIVL is aware of strategies that some researchers are employing to provide more consumer access to research findings, there is still a great deal of work to be done to ensure effective access for the majority of consumers.

In the spirit of encouraging further discussion and action towards a set of national ethical standards, AIVL has developed the following suggestions in relation to the responsibilities and obligations of researchers during the dissemination of research findings…

a) ensuring that research results are available to consumers and consumer organisations in a timely manner and that consumers have been informed if there are any delays;

b) ensuring that consumer organisations have some involvement in and control over the dissemination of the findings within their communities/networks;

c) ensure that details of findings directly relevant to the health and well-being of individual participants should be confidentially conveyed to those individuals together with the offer of suitable counselling if appropriate;

d) ensuring that the research findings are presented in a range of formats to support consumer access including but not limited to consumer magazines and newspapers, community radio talk-back, regular updates, newsletters, forums and informal meetings, sessions organised by consumer organisations, etc.

e) ensuring that research findings are available in relevant community languages as appropriate;

f) ensuring that adequate resources to support research findings being presented in a wide range of formats are included in the project budget including resources to support consumer organisations to take an active role in the dissemination of research findings.

3.3.4 Uses Research Data:

In research involving injecting/illicit drug users, how research findings are reported and used can have critical implications for the ongoing health, wellbeing and safety of

injecting/illicit drug users. The fact that a great deal of research in this area involves detailed reporting on illegal activities means that great care needs to be taken with the ways in which the data is used, presented and subsequently interpreted. In this area research, there can be very fine lines between reporting on under-explored health issues and inadvertently providing law enforcement officials with new intelligence data. As outlined in the sections above on data analysis and reporting and dissemination of findings, AIVL believes that the solution to this issue relies on researchers always remaining focussed on the key aim of improving the health outcomes for consumers. AIVL believes that every time research data and findings are used, researchers need to ask themselves critical questions about the costs and benefits to consumers of using or applying the data/findings in that context. If there is a risk of negative outcomes for consumers, then at the very least, consumers organisations should be given the opportunity to provide a consumer perspective on the value and potential impacts of using data in that context. AIVL believes that the needs and rights of consumers should always guide action this area.

In the spirit of encouraging further discussion and action towards a set of national ethical standards, AIVL has developed the following suggestions in relation to the responsibilities and obligations of researchers in relation to the uses of research findings…

a) ensuring that consumers and consumer organisations involved in the research process are also consulted and involved as appropriate, in the implementation and application of research findings including any subsequent research;

b) that when considering the application or use of any research findings the costs and benefits to consumers are assessed and findings should only be applied in the context of treatments, programs and service delivery if there is a demonstrated potential for the findings to improve the health and wellbeing of consumers;

c) that should the media solicit comments from researchers, once their work is in the public arena, researchers should have a prepared media strategy developed and should also refer the media to appropriate consumer organisations for further comments from the consumer perspective. Comments to the media should be sensitive and professional and should only focus on the research issues under consideration. Special care should be taken when giving the media comments and information about injecting/illicit drug users that could threaten the confidentiality and safety of those involved in the research. It is important for its ongoing reputation that research concerning injecting/illicit drug users does not have the unintended negative consequence of becoming a defacto or backdoor method of collecting police intelligence or other information relating to the illegal status of such activities.

d) that if a researcher wishes to use any information, photographs, video or audio recordings gathered during the project for any purpose other than that for which consent was originally obtained, further permission should be sought from the participants involved. This should include public presentations at conferences and other public forums;

e) if a researcher wishes to use the information or blood or tissue samples gathered in the course of research for any purpose other that that for which consent was originally given, further permission should be sought from the individuals involved;

4. Conclusion

Although, as identified throughout this statement, there has been some recent progress in relation to ethical issues in research involving injecting/illicit drug users, AIVL believes that there is still a great deal of work that needs to be done. In developing this statement, AIVL has attempted to identify some of the key ethical research issues from the consumer perspective. We do not profess to represent the full range of stakeholder perspectives on this issue and we are aware that there are other issues in relation to ethics and research, mostly from the researcher perspective, that have not been adequately addressed in this statement. As stated in the introduction however, this statement is not intended to be read as a comprehensive set of guidelines but rather as a discussion document to support and encourage further debate and action.

AIVL believes that a formal set of ethical standards or guidelines in relation to research involving injecting/illicit drug users are desperately needed and well overdue, however, we do not believe that such standards can be developed by one organisation in isolation. Based on the issues raised throughout this statement, AIVL is seeking support from the main government advisory structures in this area, that is, ANCAHRD and the ANCD, to initiate a comprehensive and collaborative process to develop a set of national standards. AIVL believes that a strong partnership based approach to the development of national ethical standards will ensure that there is ownership and support from all of the key stakeholders. Ultimately, the successful implementation of the national ethical standards will rely on the commitment that the stakeholders bring to the process of developing the standards and their shared desire to ensure that the research involving injecting/illicit drug users is always ethical and valuable.

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