



Ethical challenges in
drug epidemiology: issues,
principles and guidelines

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Preface

The Global Assessment Programme on Drug Abuse (GAP) *Toolkit Module 7: Ethical challenges in drug epidemiology: issues, principles and guidelines*, was prepared by the United Nations Office on Drugs and Crime as part of the activities of GAP. The main objectives of GAP are to help countries to (a) collect reliable and internationally comparable data on drug abuse; (b) build capacity at the local level to collect data that can guide demand reduction activities; and (c) improve cross-national, regional and global reporting on drug trends.

At the Global Workshop on Drug Information Systems: Activities, Methods and Future Opportunities, held in Vienna in December 2001, ethical issues in drug epidemiology were identified as a priority area, in particular with respect to registers and biological testing and for regions where institutional procedures for protecting ethical standards did not exist. It was agreed that development of ethical guidelines for collection of information on illicit drug use would be beneficial in that regard. In response to that identified need, an ethics module was planned for inclusion as part of the GAP Epidemiological Toolkit.

The GAP Epidemiological Toolkit has been produced to help States Members of the United Nations to develop systems for the collection of drug information that are culturally appropriate and relevant to their country. The Toolkit is also intended to help States to ensure that existing drug information systems conform to internationally recognized standards of good practice and focus on harmonization of drug abuse indicators. *Toolkit Module 7* forms one component of a compendium of methodological guides that have been developed to support data collection activities. Other modules provide support in the following areas: developing an integrated drug information system; indirect prevalence estimation techniques; school surveys; data interpretation and management for policy formation; basic data manipulation using a statistical software package for the social sciences; and focus assessment studies using qualitative research methods.

Other GAP activities include providing technical and financial support to establish drug information systems and support for and coordination of global data collection activities. For further information on GAP Epidemiological Toolkit modules, contact GAP by e-mail at gap@unodc.org, visit the web site of the United Nations Office on Drugs and Crime at www.unodc.org or contact the United Nations Office on Drugs and Crime, P.O. Box 500, A-1400 Vienna, Austria.

The philosophy behind the Toolkit is to provide a practical and accessible guide for implementing data collection in core areas. The Toolkit is designed to provide a starting point for the development of specific activities, referring the reader to more detailed information sources on specific issues, rather than being an end resource in itself. GAP Toolkit modules are based on principles of data collection that have

been agreed upon by an international expert panel and endorsed by States Members of the United Nations. Models used in the Toolkit are based on existing working models that have been found to be effective; however, a key principle is that approaches need to be adapted to meet local needs and conditions.

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Introduction

Chapter I

KEY POINTS

- Epidemiological research has played a key role in the response of public health institutions to the harm caused to individuals and the community by misuse of illicit drugs.
- The epidemiology of illicit drug use raises a unique set of ethical challenges that have not yet been resolved and at present there is no agreement on a framework for analysing ethical dilemmas.
- The epidemiology of drug use has been developed in industrialized societies and employs a diversity of methods in many different settings. The increasing application of these methods to the study of drug use in developing countries highlights the need for locally appropriate ethical frameworks.
- Collaborative approaches to ethical problem solving and awareness of alternative ethical perspectives are as important to epidemiologists as knowing the advantages and disadvantages of different epidemiological techniques.
- Research on illicit drug use involves the collection of sensitive personal information (often about illegal acts) from vulnerable populations. Studies that fail to protect the privacy and confidentiality of study participants are likely to produce data of uncertain reliability and validity.
- Discussions about the ethics of drug epidemiology are fundamentally discussions about civil liberties, human rights and justice.

Purpose

The purpose of the present *Toolkit Module 7* is to introduce key ethical principles and to discuss how they can be applied in

epidemiological research on drug use. Major ethical challenges for drug epidemiology are identified, along with the important questions and issues that investigators should consider in addressing those challenges. In recognition of the increasing application of drug epidemiological methods in developing countries, where institutional ethics systems may not be the norm, the Module also provides suggestions about ethics approval processes that may be used in such contexts. The Module aims to enhance the capacity of researchers in developing countries to carry out data collection on illicit drug use in an ethical manner. It is intended as a starting point for the development of an ethical framework for drug epidemiology and also as a resource that investigators may utilize when taking the initiative to develop ethically sound solutions to the dilemmas they face locally. Readers may obtain further details and guidance on the issues raised in the module from the key references cited throughout and the separate list of online resources and international organizations.

Background

The mortality and morbidity caused by the misuse of alcohol, tobacco and illicit drugs represents a significant burden to public health [1-2]. A key part of the public health response to drug problems in developed societies is the collection of epidemiological and social science data to define populations that are at risk, the identification of opportunities for intervention and the evaluation of the effectiveness of different policies in preventing or treating drug misuse and drug-related harm. The systematic use of epidemiological and social science research methods to study illicit drug use is barely 40 years old in the United States of America and the United Kingdom of Great Britain and Northern Ireland, which have pioneered the approach.

Epidemiological research on illicit drug use raises a unique set of ethical challenges [3-5], which are only beginning to be explicitly addressed. These include questions about confidentiality of information, the privacy of participants, sharing of data and the role of epidemiology in public health advocacy. Although a number of guidelines on ethics have been proposed for epidemiologists, thinking about the ethics of epidemiology is still in its infancy and there is as yet no consensus on core ethical values [5].

More generally, ethics are often not widely understood in the public health field [6-8] and no framework for analysing ethical dilemmas has been agreed upon in the public health field [9]. There is a similar scarcity of critical discussion of either the ethical underpinnings of research into addiction or how to deal with its day-to-day ethical challenges [10]. Moreover, the increased use of drug information systems and rapid assessment methods in drug epidemiology has, for the most part, occurred in a theoretical vacuum [11]. A conspicuous example of this lack of analysis has been the failure to develop an ethical framework for drug epidemiology.

Elements of epidemiological research on drug use

The boundaries of epidemiological research on drug use and drug addiction are not sharply defined. A detailed description of drug abuse epidemiology and data collection sources can be found in *GAP Toolkit Module 1: Developing an integrated drug information system* [12] and in related documents available at the United Nations Office on Drugs and Crime web site (www.unodc.org). Drug epidemiology includes surveys of patterns of licit and illicit drug use in the community that define populations at risk [13]. It also encompasses longitudinal studies of the personal and social factors that predict the course of drug use [13-14]. Drug epidemiology also includes studies of the prevalence and correlates of drug dependence in the general population using standardized diagnostic interviews [15]. Observational studies of treated populations using administrative and health record systems are also methods used by drug epidemiologists to examine rates of mortality, morbidity and abstinence among drug-dependent persons [16]. In the past decade, drug epidemiologists have increasingly applied a mix of quantitative and qualitative social research methods, often in combination as in rapid situation assessments [17]. These have included key informant interviews, focus groups and in-depth interviews, in combination with traditional methods such as cross-sectional surveys, case record analyses, telephone interviews and surveys conducted by correspondence. Participant observer and observational methods developed by ethnographers have also been employed successfully in studies of drug use.

Epidemiological research on drug use can occur in a variety of settings. In addition to the more usual community and school settings, such studies may now include the work place, street or public settings, prisons, drug treatment facilities and other health and welfare organizations, emergency rooms, hospitals and police stations. Such research may also include diverse target groups, such as the general population, youth, sex workers, homeless people, homosexual men, indigenous peoples, etc.

Epidemiological research on drug use has largely been developed in industrialized societies that have had substantial problems with illicit drug use in their large cities and that have the societal resources to devote to studying illicit drug use. Ethical issues raised by such research have been dealt with by the institutional ethics committees that evolved to regulate medical and behavioural research. As the potential morbidity and mortality associated with illicit drug use has become more internationally recognized, so too the application of epidemiological research methods has become increasingly global. The spread of such research beyond the settings in which it originated has raised questions about the role to be played by ethical systems that are different from those that have developed in the Western biomedical tradition. Resolving those issues will be critical for successful international collaboration in drug epidemiology. Taking a collaborative and open approach to ethics will also encourage the ethical challenges that are raised in epidemiological research on drug use to be viewed through many lenses, the result of which should be an improvement in resolving ethical problems. For epidemiologists, an awareness of

“alternative ethical arguments has become as important as knowing the advantages and disadvantages of different epidemiological techniques” [9].

Why ethics is important in drug use epidemiology

Since the end of the Second World War, the world has witnessed the adverse effects of unethical experimentation on vulnerable groups using invasive medical interventions. Examples include medical experimentation by the Nazis, the Tuskegee syphilis study and clinical trial deaths. These unethical practices prompted the development of national and international guidelines for ethical medical research with human beings. Institutional ethics committee systems and frameworks for the oversight and regulation of such research have also become routine in most developed societies and, while there has been some recent debate about the efficacy of such systems, nonetheless they remain the most common form of independent ethical review. Many countries now have national institutional processes to protect the rights of participants in medical research that are enforced through obligatory compliance with the World Medical Association Declaration of Helsinki (available on the Internet at www.wma.net), or local ethical frameworks that are consistent with the principles set out in the Declaration.

The conduct of drug use epidemiology differs from more traditional biomedical research in that it rarely involves invasive medical interventions that may directly harm or benefit study participants. Rather, it usually involves the collection of personal information, including information on drug use, from study participants. The principal potential harm from epidemiological research on drug use exists from the possibility that sensitive information on drug use and other illegal and stigmatized behaviour could become known to a third party, who could use it to the detriment of the study participant, that is, it may lead to their being discriminated against or, in some circumstances, to criminal prosecution. Participants in epidemiological research need to be protected from such an outcome. Discussions about the ethics of drug epidemiology are in many ways also discussions about civil liberties, human rights and justice.

Ethical principles of respect for confidentiality and avoiding harm to research participants should be respected in their own right, but there are also compelling non-ethical reasons for doing so. Drug epidemiological research that fails to observe these principles is likely to produce data of uncertain reliability and validity, because many drug users may decline to participate resulting in biased samples. Those who do participate in studies where confidentiality and other risks exist may be less forthcoming or even deliberately misleading about their drug use. Such research will have limited credibility in the scientific community and could potentially lead to misinformed drug policies and responses. Reliable and valid data on drug use requires well-designed epidemiological research that is conducted in accordance with ethical standards.

Ethical principles

Chapter II

KEY POINTS

- While there is little consensus on the most appropriate ethical theory for guiding actions that are “good” or “right”, a number of ethical principles developed for biomedical research are accepted by most people and underpin most international ethics guidelines for research with human beings (for example, respect for autonomy, beneficence, non-maleficence and distributive justice).
- These principles alert us to important ethical issues and conditions for ethical research (for example, independent ethical review, informed consent, protection of privacy and confidentiality of information, maximization of research benefits and special protection for vulnerable participants), but they do not solve all ethical problems or guide behaviour in all situations.
- Making decisions about what is ethical behaviour requires more than simply following accepted rules and principles. The rules and principles must be applied and tested in specific cases by a participatory process of debate and discussion between key stakeholders.
- The process should strive to identify solutions to ethical challenges that are suitable for the particular setting in question, rather than seeking to impose predetermined solutions. Existing rules and principles are used as a starting point for discussion and guide for prompting the discussion that will produce decisions about appropriate action.

There is little consensus among ethicists on the most appropriate ethical theory to use in deciding what acts are “right” or “good” or how individuals should act in difficult cases [18-19]. There are, instead, competing ethical theories. These include “utilitarianism”, which is the ethical theory that individual actions or moral rules should be judged according to their net consequences for good or

ill [20]. Major competitors for utilitarianism are deontological, or duty-based, ethical theories, which propose that actions should be guided by broad ethical principles or duties, such as, not treating human beings as a means to an end or behaving towards others as we would wish them to behave towards us [21].

Since there is no widely accepted theory of ethics, making decisions about what is ethical behaviour requires more than simply following accepted prescriptions and principles [22]. A number of ethical principles have been suggested as a platform of common moral ground that can be accepted by most people. These include autonomy, beneficence and others, which are discussed below. These principles alert us to the existence of important ethical issues, but they do not solve our ethical problems or necessarily tell us how to behave. These principles must be applied and tested in specific cases by a process of debate and discussion. This approach to applied ethical analysis is an appropriate initial response to the need for development of ethical standards in drug epidemiology. However, the fact that these principles were primarily developed in European and English-speaking countries means that they would need to be adapted for discussion of ethical issues that arise for research in developing countries.

Ethical analysis in drug epidemiological research, particularly for developing countries, requires a participatory process of discussion and debate between key stakeholders. It should strive to identify solutions to ethical challenges that are suitable for the setting in question, rather than seeking to impose predetermined solutions. Existing rules and principles are used as a starting point for discussion and as a guide for prompting the discussion that will produce decisions about appropriate action.

Core principles

An influential set of moral principles in Anglo-American bioethics has emerged from ethical analyses of biomedical research [4, 23]. These are the principles of autonomy, non-maleficence, beneficence and justice [18]. They have been derived from and inform many internationally recognized guidelines for the ethical conduct of research with human beings [4, 18]. Although initially derived to deal with ethical issues arising in human biomedical experimental research, these moral principles have been increasingly applied to all types of research with humans, including social, behavioural and epidemiological research.

Respect for autonomy

Respect for autonomy means that the actions of rational persons must be respected and must not be interfered with. Such persons, who are usually adults in most cultures, are assumed to be able to decide freely on a course of action without being

coerced or forced. In the contexts of medical care and biomedical research, the principle of respect for autonomy is generally taken to require (a) that research participants give informed and voluntary consent to participate in a research study; (b) that assurances are provided that the confidentiality and privacy of any personal information that they provide will be respected; and (c) that researchers will be truthful with them about the risks that may arise from their study participation [18].

Non-maleficence

The principle of non-maleficence simply means to “do no harm”. Non-maleficence requires that one should refrain from causing harm or injury or from placing others at risk of harm or injury. In biomedical research, the principle requires researchers to minimize the risks of participation in research [4, 18]. Telling the truth is also relevant to the principle of non-maleficence. Failing to give full information about the risks of participation in research violates the principles of respecting autonomy (by not telling the truth) as well as that of non-maleficence.

Beneficence

The principle of beneficence requires that research studies have a reasonable chance of producing benefits and that the benefits of research outweigh any burdens or risks of participation. In biomedical research, this means not only that the benefits of the research to society outweigh the risks but also that the risks for individual participants are outweighed by the benefits of their participation.

Distributive justice

In the case of research, the principle of distributive justice requires a fair and equitable distribution of the burdens and the benefits of research participation [4]. A fair and just research policy would aim to ensure that the risks of research participation are not unfairly distributed, for example, that they are not confined to the poor and indigent, and that any benefits of research participation, for example, access to promising new treatments, are fairly shared between all potential beneficiaries.

Ethical requirements for human biomedical research

A prolonged debate about the applied ethics of medical research conducted over the past half a century has produced a consensus on a series of basic requirements for ethical biomedical research with human subjects [4, 22]. In most developed

countries, national ethical codes set out ethical obligations for investigators, which must be adhered to in order for any research to be ethically and scientifically legitimate. Although conditions for ethical approval may differ in detail from country to country, a basic set of ethical requirements is found in most national guidelines [4]. These include (a) independent ethical review of research proposals; (b) informed consent to participate in research; (c) protection of privacy and confidentiality of information; and (d) special protection for vulnerable participants, such as physically or cognitively impaired patients, the terminally ill, children, ethnic minorities, prisoners, etc., [4]. These requirements are outlined broadly in the sections below, prior to discussing their particular relevance for drug use epidemiological research in chapter III.

Independent ethical review of risks and benefits

In order for any research with human beings to take place, investigators must obtain ethical approval from an independent committee of ethical review. This is usually an institutional ethics committee, although the terminology differs between countries. In the United States, for example, these are known as institutional review boards, while in Australia they are called human research ethics committees. The ways in which these committees are constituted and how they operate differs also. Their major aim is to provide an external review of a study protocol to provide an independent assessment of whether the benefits of the proposed trial outweigh its risks to participants [4].

Free and informed consent

Informed consent is an essential condition of ethical research. Obtaining such consent to participate in a research study involves asking potential participants to consent to their participation after they have been given a detailed description of events that will occur in the course of the study, including a description of the risks and adverse events that may occur, and have been given an opportunity to ask questions [4]. For informed consent to be given freely, subjects must know that they can decline to participate without suffering any adverse consequences. The participation of persons under the age of 18 years normally requires the consent of a parent or guardian, often along with the assent of the young person. Any uncertainty about risks of participation must be accurately communicated to potential participants and any adverse events that do occur must be closely monitored, with medical care provided promptly to treat any adverse outcomes.

All forms of consent must be given after the participants are informed of what their involvement in the research will require of them. Research participants should have time to reflect on and consider their obligations at each stage of the consent procedure. Ideally, the consent process would include a third party, usually a person not involved in the study, to ensure the integrity of the consent process. Participants

must be allowed to withdraw at any time and this option must be given to participants at all stages of the research. The decision of a research participant to withdraw must be respected and participants must be informed that they will not suffer any consequences, such as refusal of routine counselling or medical care, if they do withdraw [4]. The data collected from a participant must be omitted from the final results if they withdraw from the study.

The conditions under which persons are recruited into a study must also avoid any form of coercion or excessive inducement to participate [4]. In recent years, it has become more common to reimburse participants for their involvement in some studies, for example by giving a cash payment, vouchers for goods and services, cinema tickets, prize draws, travel costs, etc. Common justifications are that payments maximize initial recruitment and retention of participants in a study and that small payments are necessary to compensate participants for the time they spend participating in a trial or for their travel expenses. Often, however, cash payments in particular are interpreted by potential study participants as rewards for the risks or potential harm. Under these circumstances, vouchers and money serve as inducements for participation rather than as acceptable reimbursements for time and travel costs. However, some have argued that payments are ethically acceptable if they recompense a participant for the inconvenience so long as it is not seen as a payment for any harm caused [23].

Privacy and confidentiality

The privacy of trial participants is another ethical obligation that should be respected in any research. Personal information concerning a participant must not be divulged to any individual or group of individuals without the direct consent of the participant and the identity of participants should not be discernable from the published results of the study [4]. These rules are accepted as necessary components of ethical clinical trials in biomedical research on human beings by experienced investigators, but violations may still occur and must be guarded against, especially when the patient has a stigmatized condition such as a mental illness or drug dependency.

Vulnerable research participants

Research involving persons who are cognitively or physically impaired or in a dependent relationship with investigators, such as clients, students or patients, requires special ethical consideration [4]. The most widely discussed and arguably most complex issue in such cases is whether vulnerable persons are capable of providing informed consent, specifically whether they are able to (a) understand the rationale for a research study; (b) understand exactly what is required of them and why; and (c) give their free and informed consent to participate in the study [24].

Various views exist within the scientific community on the ability of vulnerable persons to participate in research studies and the capacity of such persons to consent to becoming a research participant. A generally accepted model of practice is one that recognizes, caters for and protects the special needs of an individual and minimizes or eliminates any potential harm associated with the study [4]. Usually, there are three elements to the ethical framework that is used when recruiting vulnerable persons for biomedical research. First, vulnerable participants must usually benefit from the research, that is, any treatment offered to vulnerable persons must be of potential benefit to them. Secondly, vulnerable participants must not usually be exposed to more than a minimal risk of harm. Thirdly, the treatment must be more effective than any available treatment.

Ethical issues in drug epidemiological research

Chapter III

KEY POINTS

- As a relatively new and emerging field of research, there are reasonable concerns about the applicability of broad ethical principles and standards to drug use epidemiology and growing consensus that solutions to specific ethical challenges must be developed locally.
- Investigators should consider how existing ethical guidelines (developed in a particular cultural context) can be applied in developing countries that may have either very different or no research traditions and may not have established a form of institutional or independent ethics review.
- Major ethical challenges exist for drug use epidemiological research, many of which remain unresolved, leaving open the possibility of serious ethical breaches. Significant issues exist in the following areas: capacity and limits of consent; confidentiality, privacy and protection from legal hazards; safety; opportunistic research; communication of study findings; and researcher training and understanding of the social, economic and political context in which their work is conducted.
- The ethical challenges posed by epidemiological research on drug use are amplified when attempting to conduct comparative epidemiological studies across different cultures, in particular in jurisdictions with little or no research tradition and none of the institutional infrastructure for ethical oversight.
- The conduct of drug epidemiology requires flexibility and pragmatism on the part of investigators and a commitment to identifying ethically sound solutions to the dilemmas they face locally.

Ethical challenges in drug use epidemiology

In many developed countries, the institutional research ethics committees that oversee human research typically adhere to the broad ethical principles outlined in the previous chapter when making a decision on the ethical acceptability of biomedical, clinical and social research. There are reasonable concerns about the applicability of such principles and standards to new and emerging fields of research, such as drug epidemiology. General ethical principles often fail to provide specific guidance in dealing with the complexities and ambiguities of ethical challenges that arise in everyday practice [25]. There are also questions about how such standards and guidelines, which have been developed in a specific cultural context, may be applied in developing countries, which may have either very different or no research traditions and may not have established a form of institutional ethics review.

Epidemiological research on drug use and associated harm exemplifies many of these concerns. These are illustrated below by considering some major ethical challenges in drug epidemiology. Many of these ethical challenges remain unresolved, leaving open the possibility of serious ethical breaches. What is needed is an open and inclusive approach to the task of defining how the ethical principles and requirements that have grown from biomedical research apply in this field.

In the following discussion, the intention is to highlight significant ethical challenges, rather than to provide an exhaustive analysis of ethical issues that arise in epidemiological research on drug use or to resolve those issues. With continued evolution of epidemiological methods and the quickening development of communications technology, new ethical challenges will arise in the future. It is hoped that the present module will provide a useful frame of reference from which to address both existing ethical challenges for drug epidemiology and the unforeseen new challenges.

Free and informed consent

The adequacy of informed consent is commonly assessed in relation to questions about the level of information provided to participants about research procedures and the associated risks, benefits and safeguards; types of information delivery, taking into account literacy levels and preferred communication modes; opportunities for participants to voice concerns and ask questions; the extent to which consent is free from duress, undue influence or intimidation; and who may rightfully provide consent in accordance with local traditions.

Free and informed consent to participate in epidemiological research does not present any special problems for autonomous adults who can understand the nature of their participation and can freely decide to be involved or not. It presents more of an ethical issue for epidemiological studies of adolescents, which are increasingly being carried out because adolescence is when drug use often begins [26]. The participation of adolescents in any form of research usually requires parental consent

and adolescent assent [4]. Obtaining such consent can be cumbersome in school-based surveys of drug use, which is an efficient way of conducting surveys on drug use. Typically, low response rates and underrepresentation of minority groups has prompted researchers to use a method of “passive parental consent”, which informs parents that a survey is to be done via a circular that invites them to object to the participation of their child. It is then assumed that the absence of parental objection means that the child can be included in school surveys. This approach requires further ethical justification and discussion.

Deciding whether drug-dependent people are vulnerable persons

An issue of concern in epidemiological research on drug use and addiction is whether persons who are drug dependent have an impaired capacity to consent to participation in research [27-28]. It is an issue that has rarely been discussed in the addictions field. Much of the recent controversy about research on vulnerable populations has been about experimental and clinical research on persons who are cognitively impaired, for example because of serious mental illnesses such as schizophrenia [28] or other causes such as having suffered a stroke [29]. In such cases, there are serious doubts about the capacity of some patients to give free and informed consent, because they are intermittently or permanently cognitively impaired. Analogies between such cases and issues in research on persons who are drug dependent are considered below.

It would probably be generally agreed that addiction in itself does not impair in the same way or to the same degree as acute schizophrenia. Nonetheless, drug-dependent persons may be vulnerable to coercion and inducement to participate in research when they are intoxicated or when they are experiencing acute withdrawal symptoms [27-28]. Persons who are severely intoxicated by some drugs, such as alcohol or cocaine, could reasonably be said to be suffering from impairments similar to those of a person who is psychotic. Similarly, a drug-dependent person who is in the midst of acute withdrawal symptoms could be induced to consent to participate in research in order to obtain their drug of dependence or medication that would relieve their withdrawal symptoms [27-28].

Informed consent issues exist for research involving participants who may be intoxicated or who may have an acute drug-induced psychiatric condition [30]. There has been little discussion in the addiction literature of the implications for consent, autonomy and voluntariness of recruiting intoxicated persons in drug research. Few records are kept as to the intoxicated state of research participants in drug epidemiology studies, although it can be noted from experience that it is not unusual in illicit drug research for a small proportion of participants to be intoxicated to some degree during interviews.

The College on Problems of Drug Dependence has suggested that informed consent should not be obtained when prospective participants are intoxicated, in withdrawal

or cognitively impaired [27]. However, it is unclear how a state of intoxication or impairment may be reliably determined. Moreover, if the study target group for epidemiological research comprises frequently intoxicated persons, it may be arguable that it is preferable for reasons of study validity to recruit such participants. The question of whether that is ethical may depend on the demands placed on participants, whether the level of intoxication of an individual could have a negative impact on comprehension and performance as research participants and the risks that they may be exposed to because of their participation, such as increased intoxication and risk of overdose. It is clear that, from time to time, the conduct of drug epidemiology requires flexibility and pragmatism on the part of investigators. Some of the important ethical questions to be considered are whether intoxication should be an absolute exclusion criterion; how to deal with participants who are intoxicated but lucid; how researchers should judge the extent of impairment; how reliable such judgements would be; and in what circumstances proxy consent might be considered appropriate.

Payment to research participants

The payment of participants in epidemiological research on drug use raises questions about voluntary consent. In Australia, for example, it has been common practice since 1984 for researchers to pay drug users who participate in research interviews. It has proved a successful way of recruiting illicit drug users for a variety of studies. It is also standard practice in drug research in the United States [27]. While the bioethics literature has explored the ethics of paying research participants [31-34], it has not yet considered the special issues raised by paying drug users for research involvement. Critics of the practice are concerned that cash payments will serve as an inducement because the money could be used to buy drugs [26]. Non-cash payments, such as vouchers, prize draws, food and refreshments, have been suggested as more appropriate for drug users.

Advocates of cash payments argue that payment for research participation is an ethical practice in that it reflects the ethical principles of respect and dignity [31, 35]. Non-cash methods, they argue, reinforce negative drug-user stereotypes and reflect a paternalistic view of the capacity and rights of users to make their own choices. The issue is controversial and remains unresolved in epidemiological drug research. Specific aspects that require attention include the suitability of various ethical frameworks for understanding research participant motivation; the relative weight placed on various motivations for research involvement; definitions of inducement; quantification of the value of time and out-of-pocket expenses; acceptability of different mechanisms for reimbursement; and analysis of the risks and harm that may arise from reimbursement practices.

A key consideration in this regard is the potential for payments to increase the risks to participants. This is a particularly pertinent issue when drug-dependent persons who might be experiencing withdrawal symptoms are recruited to drug

epidemiological studies. In such cases, monetary payment might be seen as an inducement to participate because it enables the person to fund the purchase of drugs to alleviate their withdrawal symptoms. The concern is that persons in this predicament may ignore any risks that participation entails that would in other circumstances make them much less inclined to participate.

In order to avoid these problems, studies may need to consider screening participants for withdrawal symptoms when assessing their suitability and obtaining their informed consent [27-28]. Other strategies to consider include not advertising cash payments when recruiting participants and providing each cash payment immediately after informed consent has been obtained and prior to interview/survey commencement in order to avoid any suggestion that the prospect of payment is being used to coerce participation. Until more consensus exists on this issue, payment to participants will need to be approached on a case-by-case basis in accordance with local circumstances and ethical values.

Confidentiality, privacy and legal hazard

It is critical in drug epidemiological research to protect the privacy of participants and the confidentiality of any information that they provide. Some types of drug use (for example, cannabis, cocaine and heroin) are illegal in any context and the use of some drugs is illegal in some age groups (for example, alcohol use by persons who are under the minimum legal age). Drug use surveys may also ask about illegal and stigmatized acts, such as driving while intoxicated, selling illegal drugs or engaging in theft, fraud or violence to finance drug use. If such data were linked to individuals by law enforcement officials then the study participants would face criminal charges. In the United States, certificates of confidentiality can be obtained by researchers in order to provide participants with an assurance that this will not happen. The situation in most other countries is much less clear [36-37].

Issues of confidentiality and privacy also arise from collaborative research in which research data may be shared with law enforcement agencies or law enforcement data may be linked with health data. Special care needs to be taken in such settings to prevent study participants from being identified. Ensuring the confidentiality of research information is less of a problem when data are collected in a single cross-sectional interview and no identifying information, such as a name or other unique identifier, is obtained. In such a scenario, special attention needs to be given to informed consent procedures. Assurances of confidentiality should not be given to participants if written consent, that is, signed names, is obtained. Researchers may instead wish to obtain verbal consent or to give participants the opportunity to use pseudonyms. Ensuring confidentiality becomes much more of an ethical issue in longitudinal studies, where multiple contact details may be collected so that individuals can be re-contacted for follow-up interviews months or even years later. Standard precautions are to store names and identifiers and the survey data separately and securely.

Even when such protective measures are taken, researchers in some countries may be compelled by courts to provide research records to law enforcement officials. Concerns about confidentiality also arise in the case of field research, where face-to-face interviews may occur in public places such as the street, parks and cafes. In small communities, this may create a potential risk to participant confidentiality, particularly if the investigator is a known drug researcher or if the conversation is overheard.

Confidentiality is potentially a major ethical issue if biological samples such as blood are taken from a participant. DNA, which can be extracted from such samples, provides a unique identifier for all individuals (except identical twins). It could, if linked to data from questionnaires or interviews, permit individuals to be connected to self-reported illegal acts. The same issues are raised by the use of case registers and clinical databases, such as treatment registers or registers that link information on treatment, arrest and other reports concerning people who use drugs.

Special legal protection and research precautions will be necessary to protect privacy in such cases. The implications for drug epidemiology of recent changes in legislation on health privacy and data protection in a number of jurisdictions will require careful monitoring and drug epidemiology researchers should be aware of these [38]. In some cases, for example in jurisdictions where legislation requires the identification, tracking and reporting of drug users, minimum guarantees of confidentiality cannot be given to participants. In such cases, researchers should seriously consider the option of not doing the research.

Safety issues

Interviews with illicit drug users occur in settings that may be potentially dangerous for researchers [39]. In order to protect participant confidentiality in face-to-face surveys in the field, illicit drug users are often interviewed in settings out of the public gaze. While generally inadvisable, interviews may occur late at night, in the residence of the participant or in other settings in which the safety of the researchers cannot be guaranteed.

Twelve steps for safety

1. Clarifying responsibilities

- Between employers, managers, employees, field site staff and research participants.

2. Budgeting for safety

- Infrastructure and other project costs, such as training, insurance, field-work costs, car rental and room fees.

3. Planning for safety in the research design

- Choice of methods and interview sites, for example, alternatives to home visits.
- Staffing, for example, working in pairs, training, staff attributes and experience and research design.
- Recruitment methods, for example, prior telephone contact to assess circumstances.
- Timetabling, for example, the impact of intensive or late-night work on capacity to assess risks and to handle incidents.

4. Assessing risks in the fieldwork site

- Field site issues, such as transport options, contact points, accommodation and local issues.
- Preparation, for example, explaining research to local statutory and community leaders.

5. Risk associated with participants

- Anticipate and plan for negative reactions from participants, for example, in case of specific, sensitive topics and for participants with particular characteristics.
- Be aware of issues of gender, culture and race.

6. Setting up fieldwork

- Be informed about the participant group and their environments and local issues, for example, the history of research in the setting.

7. Interview precautions

- Minimize risk and plan for action if an incident arises, for example, travel arrangements, dress code, cold-calling and first contacts, home visits, exit routes, escorts, personal alarms and mobile telephones, safe interview spaces, researcher identification and authenticated badges or cards.

8. Maintaining contact

- Maintain contact between the office and fieldwork sites. Leave details of the itinerary and location with a designated contact person, notify changes, make mobile telephone contact prior to and after interviews or at the end of the fieldwork session/day.

9. Conducting interviews

- Researchers must have training on cultural norms, gender dynamics of interaction, body language, social distance, challenges and limits.

10. Strategies for handling incidents

- Training and interpersonal skills are important, for example, to handle threats, abuse or compromising situations, in mobile telephone use, paying attention to amount of cash carried, assessing the impact of sensitive topic discussions, putting in place a protocol for termination of interviews.

11. Debriefing and support

- Reporting, discussing and responding to serious incidents is essential.
- Researcher support mechanisms (formal and informal) must be in place.

12. Maintenance of guidelines

- Keep in mind safety issues in training and induction of new staff, for example, providing handbooks and information.
- Ensure that reflection on adherence to guidelines and promoting safety protocols with colleagues is part of the routine.

Source: Craig, Corden and Thornton [40].

In drug research, topics of enquiry are often sensitive and may cause feelings of anxiety and discomfort for participants. Other safety issues concern the level of interviewer support, back-up and training; protocols for responding to crises that may require confidentiality to be broken (for example, suicide risks); and carrying valuable personal and research items such as a laptop, mobile telephone or cash.

Personal safety is an ethical issue to the extent that it is the responsibility of the researcher to ensure that their research and their contact with research participants and their communities, does not cause harm to research participants, researchers or community members. Safety protocols for social science research, such as the 12 steps for safety presented above [41-42], can be used to address safety issues in drug epidemiology.

Other challenges

Some epidemiological research practices may raise ethical concerns. One such practice is the opportunistic inclusion of additional questions about illicit drug use into studies designed for other purposes (known as “piggy-backing”). This approach may be indicated where more in-depth research is neither feasible nor funded, or where investigators want to minimize the burden of studies in particular target groups. However, concessions may have to be made in such an approach [26]. Careful consideration should be given to the probable impact on reliability and validity of reports obtained from participants; the need for additional researcher training; the

potential for confusion in terms of the informed consent and confidentiality assurances given for different studies; and the possibility of inducements if participants are given multiple study payments for a single interview.

Ethical concerns may also be raised by the ways in which the findings of drug epidemiological research are communicated and used in policy development and decision-making. The ethical implications of the way in which research topics are chosen and the findings are used should be explored by researchers [7]. Where appropriate, the aggregated findings of drug epidemiology studies should be made available to all stakeholders by means of copies of reports or executive summaries or by plain language summaries of main findings presented as posters, pamphlets or letters. These could be given directly to participants (with their permission), or made available at the study recruitment sites and on the World Wide Web. In deciding on the best way to make the findings available, investigators will need to weigh the availability of resources for dissemination; confidentiality issues; data ownership; and responsibility to participants and the wider community for communicating the findings of publicly funded research.

Another communication issue that raises ethical concerns is the collection of blood samples (for example, if testing for blood-borne virus infections) and risk behaviour information, such as risk practices for transmission of blood-borne viruses, overdose, etc. In undertaking serological testing, investigators should consider and clarify their obligations on reporting test results to study participants (and third parties who may be placed at risk by notifiable diseases). If individual feedback of serological tests is to be given, then counselling before and after testing and other appropriate support should be provided.

Ethics of drug epidemiological research in developing countries

The ethical challenges posed by epidemiological research on drug use within a culture are amplified when attempting to conduct comparative epidemiological studies of drug use across different cultures [3-4], especially in developing countries that may have little or no tradition of doing such research and none of the institutional infrastructure for ethical oversight that is standard in many developed societies. This work, which is in its infancy, needs to be given priority.

The application of broad biomedical ethical principles to epidemiological research on drug use may be a starting point, but there also needs to be a focus on the significant practical challenges that exist for such research in developing countries, especially in developing a local capacity for ethical analysis and the mechanisms for ethical oversight and protection of research participants. It cannot be assumed that the requirements of informed consent, confidentiality and privacy that have arisen out of debates on ethical principles in developed countries can be straightforwardly applied in all cultures and societies. For example, there are aspects of informed

consent that are particular to the conduct of drug epidemiology in developing countries. As a relatively recent development in research ethics, there are still many unanswered questions about the requirements of informed consent in these settings [43]. The relevance of issues such as participant vulnerability, levels of awareness and expectations about rights, communication difficulties, documentation issues, literacy and the rules of obtaining consent in hierarchical societies is still contested and deserves further attention [44].

In addition, issues of race, culture and gender may have an impact upon the safety of researchers, in particular when in the context of research in developing countries [41]. Non-indigenous researchers may find it particularly difficult to conduct fieldwork in such settings and yet it is often only the non-indigenous researchers who have the requisite training to do so. Training and capacity-building around technical research skills and ethical issues in drug epidemiology should be a major priority and is to be considered a core part of ethical research. Other issues arise for research participants and third parties to the research, especially in small communities where participation in research is more difficult to disguise than in the relative anonymity of larger cities. Another issue is that of monitoring the conduct of drug epidemiological research in developing countries. Consideration should be given to the special needs that exist in jurisdictions that lack local institutional ethic infrastructure to support such ethical oversight.

Ethical review of drug epidemiological research

Chapter IV

KEY POINTS

- Careful analysis is needed in considering the ethics of epidemiological research on drug use. Principles that have evolved in biomedical research provide a starting point for discussion on how existing moral principles and practical ethical standards can be applied in local settings.
- In most developed countries, the preferred method of independent ethics review of research is the institutional ethics committee. In countries where institutional ethics systems do not exist, a minimum standard of ethical review for all research with human subjects should be considered.
- Where independent ethics review systems do not exist investigators, in consultation with research stakeholders, may choose to develop a local hierarchy of ethics review options. Key factors include existence of local networks of experience and expertise; available local resources for establishment and ongoing support; and professional and other institutional endorsement and support.
- Checklists of ethical issues and key questions are a valuable tool for assisting researchers and other stakeholders in assessing the ethical acceptability of epidemiological research on drug use. Issues that should be considered are requirement for ethical review; study design; informed consent; confidentiality and privacy; potential harm; benefits; participant payment; health and safety; dissemination and disclosure; and monitoring.

The foregoing discussion demonstrates that there is currently a need for careful ethical analysis in epidemiological research on drug use. Core moral principles and ethical requirements that have evolved in biomedical research provide some guidance for drug epidemiological research, but it will not be a routine or straightforward process to

apply those rules and principles in the new setting. In considering the ethics of research in developing countries, drug epidemiologists must be sensitive to the social, economic and political context in which their work is conducted [45]. The task will also require a commitment to including the views of all stakeholders and engaging in wide-ranging, local discussions about the ethics of doing such research. The aim of the process should be to discover how existing moral principles and ethical requirements can be applied in the special setting of epidemiological research on drug use. In the present chapter, broad recommendations are provided for a process that could be adopted by investigators and others in responding to the ethical issues that arise for drug epidemiological research.

Hierarchy of ethical review

Different institutional ethics processes vary in terms of the types of research defined as requiring independent ethical review. There are instances where exemptions from ethical review may be justified, such as in some evaluation studies, quality assurance and review activities and records audits. However, in the case of drug epidemiology, where sensitive information is sought from potentially vulnerable populations, and in settings where institutional ethical protections may not exist, it is preferable to adopt a minimum standard of ethical review for all research.

In jurisdictions where oversight by an institutional ethics committee does not exist, it may be useful for investigators to consider a hierarchy of ethical review options, where the next most appropriate review option is chosen according to local circumstances (see the box presenting a hierarchy of ethical review below). For example, the minimum standard, where no other options are available, might be for investigators to pay special attention to the issues outlined in the present module, with reference to existing guidelines, charters and professional codes and with some independent advice. The “gold standard”, according to common practice in developed societies, would be independent review by an institutional ethics committee.

For researchers in developing countries, an appropriate minimum standard of ethical review might consist of the investigator and their team identifying the key ethical challenges in their research and then developing a written protocol that sets out the ethical challenges and the ways in which the team proposes to deal with them. The draft protocol could be revised after consultation with stakeholders and in the light of the past experience of the team members, local circumstances and independent expertise and advice. To aid in that process, the section below provides a checklist of ethical issues and key questions that researchers and other stakeholders should consider in assessing the ethical acceptability of epidemiological research on drug use. Sample application forms, information sheets and consent forms, etc., to support such processes may be obtained from a number of web sites, including: www.nih.gov, www.health.gov.au and www.mrc.ac.za.



A recurrent theme in the GAP Epidemiological Toolkit is the importance of ensuring that drug epidemiology methods are appropriate to the local conditions in which the research is to be done. This is an equally vital consideration in addressing significant ethical challenges that may arise in drug epidemiology. Investigators have a responsibility to consider not only the ethical issues for individual research participants, but also those that exist for the communities in which the research is undertaken and which may be affected by study findings and the ways in which they are reported and used. The development of local and international networks of experience and expertise is critical to this task. This is particularly the case for researchers who work in countries where institutional ethics committees do not exist. Alternative sources of ethical review may include ethics experts, ethicists, community leaders and other stakeholders, such as participant representative groups. In developing such a network, developing countries or regions with no access to ethics processes may consider forming a regional ethics group or a community advisory board [46-49]. Potential members could include people with expertise in the field of research being undertaken; representatives from the local clergy or religious leaders; community representatives; legal professionals; and ethicists or people with expertise in ethics. The web site of the United States National Library of Medicine (www.nlm.nih.gov) contains a bibliography concerning community consent and the web site of the World Health Organization (www.who.int) provides practical advice about establishing and running research ethics committees.

A key condition in establishing such processes is that the individuals and/or groups should be independent of the investigators. Other issues to consider include the time required and the resources needed to review multiple research proposals; potential conflict in terms of responsibilities if the ethics review processes are established

by drug epidemiologists; the efficacy of community ethics review processes and quality assurance mechanisms; and the capacity for sustainable funding and support of committees and advisory groups.

Checklist of ethical issues for drug epidemiology

A checklist of key questions and ethical issues that researchers and other stakeholders should consider when assessing the ethical acceptability of epidemiological research on drug use is presented below. It incorporates the applied ethical issues discussed in the preceding chapters, actions implicit in the core principles and additional practical issues of importance.

Key questions and ethical issues

1. Does the study need to be approved by an institutional ethics committee?

Is there a:

- (a) Funding or legal requirement;
- (b) Requirement of the local community;
- (c) Requirement for publication.

2. Does the study meet accepted ethical guidelines (international, national, local and community level)?

What level of independent ethical review has the study received?

3. Study design

Are the study methods valid, appropriate and feasible given available funding, hypotheses, aims and objectives?

4. Informed consent

(a) Is written consent necessary (see box at the end of the present chapter for a sample consent form)?

(b) Is informed consent freely given and not coerced from the participant (or third party in the case of children or tribal cultures, etc.)?

(c) Are all relevant aspects of consent covered for the study in question (namely, consent to participate, consent to access records, consent to provide information to third parties, cultural acceptability, etc.)?

(d) Is project information available to participants in an accessible plain language format? (namely, information about the nature and purpose of the study; possible risks of participation; benefits of participation; funding sources; confidentiality protections; and how information will be used and reported). Will these details be summarized verbally prior to obtaining consent?

(e) Does the study consent process advise participants about the circumstances under which confidentiality may be broken?

- (f) Are the participants old enough to give informed consent?
- (g) Is the capacity of the participant to consent impaired by intoxication, cognitive impairment or drug withdrawal? Is proxy consent appropriate?

5. Confidentiality

- (a) Are the principles of research confidentiality adhered to?
- (b) Is a minimum guarantee of confidentiality appropriate?
- (c) Will research interviews be conducted in circumstances that protect confidentiality and privacy?
- (d) Is access to the data limited to the researchers?
- (e) Will the data be used only for the designated research purposes?
- (f) Is the team aware of circumstances in which confidentiality must be broken?
- (g) If outside agencies or third parties are involved, has the team discussed any ethical issues that this may raise?
- (h) Will proposed data storage and disposal mechanisms protect participant confidentiality?

6. Potential harm to participants

- (a) Have all the potential harms been explored (for example, discrimination, legal hazard, participant distress)?
- (b) Has the study team developed protocols for preventing and managing potential harm (for example, agreements with study sites, debriefing and crisis response options, reporting requirements)?
- (c) Do the potential benefits of the research outweigh any harm?

7. Payment to participants

- (a) Will study participants be compensated and what is the rationale for doing so?
- (b) Is the proposed payment an inducement to participate or fair compensation for the demands of the study?
- (c) At what stage in the research will participants be made aware that they will receive payment and when will payment be provided?
- (d) Does the provision of monetary payment (or other types) pose additional risks to participants or to investigators?

8. Benefits from the research

- (a) Benefits to the participant?
- (b) Benefits to the wider community, including the group or collective to which participants belong?

9. Health and safety of researchers

- (a) Is the research team in agreement about the circumstances in which a research interview should be terminated?
- (b) What debriefing mechanisms are available (for example, qualified on-call counselling, informal debriefing)?
- (c) What steps have the team taken to ensure that interviews are safe for both the interviewer and the participant?

10. Dissemination and disclosure

- (a)* How will the research findings be disseminated?
- (b)* Will a report or some form of feedback be provided to participants who request it?
- (c)* In the case of serological testing and collection of information on risk practices of relevance to third parties, what obligations do the study team have for disclosure of test results, etc.?

11. Other issues for consideration in drug epidemiological research

- (a)* What are the risks of reporting criminal activity or protection issues?
- (b)* Will representatives of the participant be consulted about the research and the way in which it is conducted?
- (c)* Under what circumstances would the study be abandoned?
- (d)* Have participants been advised of any mechanism(s) for handling complaints?
- (e)* Has authorship been discussed among the team members?
- (f)* Have the researchers received adequate training on drug epidemiology ethics and other technical issues?
- (g)* Do any conflicts of interest exist (for example, funding sources and data ownership, use of drug-users as peer researchers)?

12. Ongoing monitoring

- (a)* In the case of review by an institutional ethics committee or community ethics committee, are there processes in place for reporting of ethical breaches or adverse events?
- (b)* What other steps have the study team taken to ensure ongoing attention to ethical issues?

SAMPLE INFORMED CONSENT FORM

*(Organization logo)**(Research project/study title)*

CONSENT FORM FOR RESEARCH PARTICIPANTS

(Name of investigators and affiliations)

Participant name/Pseudonym: _____

Please read the following points before agreeing to participate in this project. The researcher will go over these points with you after you have finished, to make sure all of your questions are answered.

1. I consent to participate in this project. The purposes and procedures of the study have been explained to me and are attached to this form (project information sheet).
2. I authorize the investigator or his assistants to use with me the procedures referred to under point 1 above.
3. I acknowledge that:
 - (a) The information I provide will only be seen by the people involved in the study (the research team) and I will not be personally identified since the results will be presented in anonymous group form;
 - (b) The information I provide will be confidential and kept in a locked cabinet for a minimum period of XXXX years (according to national standards). However, a serious and imminent threat to harm myself or others may be subject to reporting to a third person and any information concerning the protective safety of children is subject to reporting to relevant authorities;
 - (c) Confidentiality of the information I provide will be safeguarded except where disclosure is required, authorized or permitted under law;
 - (d) I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied;
 - (e) Whether I choose to participate or not will not affect my access to any services at XXXXX or elsewhere;
 - (f) The possible effects of the procedures have been explained to me to my satisfaction;
 - (g) The project is for the purpose of research and not for treatment.

Do you have any questions about this project?

Please sign below or provide verbal consent if you wish to participate in the project.

Participant signature (or investigator/researcher to record the conditions under which verbal consent was obtained):

_____ Date: _____

Investigator signature: _____ Date: _____

Witness signature: _____ Date: _____

Further reading and resources

Chapter V

A list of selected resources and further reading on the ethics of drug epidemiology, intended to guide the reader to key resources in addition to those cited, is provided below.

International organizations and resources

United Nations Office on Drugs and Crime (www.unodc.org)

For a detailed description of drug abuse epidemiology and data collection sources, refer to the epidemiological *Toolkit Module 1: Developing an integrated drug information system* and related documents available from the United Nations Office on Drugs and Crime.

Council for International Organizations of Medical Sciences (www.cioms.ch)

The Council for International Organizations of Medical Sciences is an international, non-governmental, non-profit organization established jointly by the World Health Organization and the United Nations Educational, Scientific and Cultural Organization in 1949 representative of a substantial proportion of the biomedical scientific community. Key resources available from its web site include the *International Guidelines for Ethical Review of Epidemiological Studies* and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, covering ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of controls in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health-care services.

World Health Organization (www.who.int)

The World Health Organization has a comprehensive web site containing sources for operational guidelines for ethics committees, rapid assessment and response guides for drug use research and other

sources on ethics in epidemiology. The site also contains valuable sources for information on the nexus between health, human rights and ethics.

Pan American Health Organization (www.paho.org)

The Pan American Health Organization is an international public health agency with more than 90 years of experience in working to improve health and living standards in the countries of the Americas. It serves as the specialized organization for health of the Inter-American System and the Regional Office for the Americas of the World Health Organization. Its web site has a number of resources on health situation analyses and epidemiological methods.

United Nations Educational, Scientific and Cultural Organization (www.unesco.org)

The United Nations Educational, Scientific and Cultural Organization promotes collaboration among States through education, science, culture and communication in order to further universal respect for justice, the rule of law and the human rights and fundamental freedoms, without distinction as to race, sex, language or religion, that are affirmed for the peoples of the world by the Charter of the United Nations. Its web site contains general resources of interest on ethics in science.

World Medical Association (www.wma.net)

The World Medical Association developed the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, which is available on its web site.

International Council for Science (www.icsu.org)

The web site of the International Council for Science includes the report of its Standing Committee on Responsibility and Ethics in Science entitled “Standards for ethics and responsibility in science: an empirical study”.

International Epidemiological Association (www.dundee.ac.uk/iea)

The International Epidemiological Association is a professional association whose web site contains a comprehensive page with links to various international organizations and resources that may be of interest to epidemiologists.

National Institutes of Health (www.nih.gov)

The bioethics resources found on the web site of the National Institutes of Health of the United States, which is maintained by the National Library of Medicine, include a comprehensive listing of resources, background information and various positions on issues in bioethics. A comprehensive bibliography with over 4,650 citations and other issues in bioethics; a section on international issues and codes, educational resources and sample informed consent forms and other relevant sample documents for the protection of human subjects can be accessed from the site.

Nuffield Council on Bioethics (www.nuffieldbioethics.org)

The Trustees of the Nuffield Foundation established the Nuffield Council on Bioethics in 1991 to identify, examine and report on the ethical questions raised by advances in biological and medical research. In addition to general ethics resources of interest, the web site contains a link to the Council publication *The ethics of research related to healthcare in developing countries*.

**The National Bioethics Advisory Commission
(<http://bioethics.georgetown.edu/nbac>)**

The web site of the National Bioethics Advisory Commission is hosted and maintained by the National Reference Center for Bioethics Literature at Georgetown University, United States. It contains a page listing publications, with links to ethics resources of interest.

South African Medical Research Council (www.mrc.ac.za)

The web site of the South African Medical Research Council contains numerous ethics resources and links of interest, including the *Guidelines on Ethics for Medical Research*, covering international collaboration in epidemiology.

National Health and Medical Research Council (www.health.gov.au/nhmrc)

The web site of the National Health and Medical Research Council of Australia contains numerous ethics resources and links, including to the Australian Health Ethics Committee, a principal committee of the National Health and Medical Research Council that provides advice on ethical issues relating to health; develops ethics guidelines for medical research involving humans; promotes community debate on health ethics issues; monitors the work of human research ethics committees; and monitors and advises on international developments in health ethics.

American College of Epidemiology (www.acepidemiology.org)

The American College of Epidemiology is a professional organization dedicated to continued education and advocacy for epidemiologists in their efforts to promote public health. The site contains ethics guidelines for epidemiology, which discuss professional roles; risk minimization and protection for research participants; provision of benefits; equitable distribution of risks and benefits; confidentiality and privacy; informed consent obligations; requirements for ethical review of epidemiological research; maintaining public trust; avoiding conflict of interest and partiality; promotion and communication of ethical requirements to colleagues, employers and sponsors and confronting unacceptable conduct; and obligations to communities.

Joint United Nations Programme on HIV/AIDS (www.unaids.org)

The Joint United Nations Programme on HIV/AIDS is an advocate for global action on HIV/AIDS. It aims to lead, strengthen and support an expanded response directed at preventing the transmission of HIV, providing care and support, reducing the vulnerability of individuals and communities to HIV/AIDS and alleviating the impact

of the epidemic. The web site contains a list of publications on human rights, ethics and law and a guidance document, *Ethical considerations in HIV preventive vaccine research*, which contains 18 guidance points, some of which are also relevant to the issues discussed in the present *Toolkit Module 7*.

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