

MODULE TWO: INFORMED CONSENT

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ABSTRACT

The objective of this module is to familiarise you with the concept of informed consent, its ethical basis, its elements, and typical problems that are encountered even by the most well intentioned researchers when trying to achieve genuine informed consent.

INTRODUCTION

Any medical treatment, healthcare activity or research requires the consent of the patient or person directly affected by such activity. This requirement is based on the fundamental moral duty that we do not act against a person's wishes, and that we respect a person's human dignity. Informed consent thus entails a shared decision by both the investigator/physician and the participant. The duty of obtaining informed consent is a requirement in research ethics, which is widely recognised in national and international guidelines as well as legislation. The international guidelines on informed consent are entailed in: the World Medical Association's *Declaration of Helsinki*;¹ and the Council for International Organisations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* prepared by CIOMS in collaboration with the World Health Organisation.² The Declaration of Helsinki and CIOMS Guidelines stipulates the essential information that must be supplied to the prospective participants.

¹ World Medical Association. 2000. *Declaration of Helsinki*. Paragraph 22.

² The Council for International Organizations of Medical Sciences (CIOMS). 2002. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*: guidelines 4, 5 and 6.

The Department of Health's (DoH) *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa*³ reiterate the specific information from the *Declaration of Helsinki* that should be supplied to the participant in the process of procuring consent. The CIOMS Guidelines that are referred to in the DoH Guidelines are from the 1993 version, since the 2002 CIOMS Guidelines were prepared after the DoH Guidelines. The Medical Research Council's (MRC) *General Principles* restate the provisions of Section 12(2) (c) of the Constitution viz., 'Everyone has the right to bodily and psychological integrity, which includes the right . . . not to be subjected to medical or scientific experiments without their informed consent.'⁴ This provision clearly indicates that no clinical trials may be carried out on individuals without their consent. Written information and consent forms are recommended in the absence of any compelling reasons. Written information may be contained in a brochure. Paragraph 5.3.2.3 of the MRC Guidelines stipulates the detailed information that the investigator must supply to the participants.

The DoH Guidelines do not specify the information to be included in the consent form, but international-based practice requires the following aspects: study title; particulars of researchers e.g., names, titles, departmental affiliations, and telephone numbers of the principal researchers and those having contact with the participant; an introductory section with basic information that has been supplied to the participant; the researcher's statement confirming having explained the nature of the trial to the participant, signature and date; and the participant's statement confirming having understood the information, names, signature and date.

WHY INFORMED CONSENT IN BIOMEDICAL RESEARCH?

Medical interventions aimed at a patient's well-being are quite different from research. Research aims at the production of medical knowledge for the good of the society at large, with the possibility of direct benefits to the participants. This distinction between research and treatment makes it ethically mandatory that participants in clinical research should volunteer to participate.

³ South African Department of Health. 2000. *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa*.

⁴ Medical Research Council of South Africa. 2002. *Guidelines on Ethics for Medical Research: General Principles*. Available at: <http://www.mrc.ac.za/ethics/ethics.htm>

Procuring consent ensures that participants are treated in a manner befitting their dignity.

The ethical basis of informed consent is the moral principle of respect for the research participants' autonomy, i.e., the competence and capacity to make appropriate decisions pertaining to the procedures involved in a clinical intervention. This principle is derived from the shared and widely accepted belief in the moral propriety of respecting the participants' autonomy in all circumstances.

Autonomy has two facets: firstly, the requirement that those who are capable of deliberating on their personal choices should be treated with respect for their capacity for self-determination; and secondly, persons with diminished or impaired autonomy, or those who are in dependent or vulnerable positions, should be protected against harm or abuse.

WHAT IS INFORMED CONSENT?

The CIOMS Guidelines give the most concise definition of informed consent, as a decision to participate in research made by a competent individual who has received the necessary information; has adequately understood the information; and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence, inducement or intimidation. (Commentary on CIOMS Guideline 4.)

Informed consent is also the ethical requirement that human participants' consent be procured before being enrolled in a clinical trial. The procurement of informed consent consists of the conveyance of full details of the trial in an appropriate and understandable format from the investigators to the participants, ascertaining the capacity of the participants to comprehend the conveyed information, and the documentation of the manner in which informed consent is subsequently procured.

The documentation of informed consent is not a substitute for the detailed process of procuring consent. 'The ethical validity of informed consent hinges not on the written word, but on the quality of the interaction between a patient and clinician and record keeping is just one part of the process. . .'⁵ Informed consent is based on mutual trust between the investigators and the participants. Documentation may not be required in some types of research, such as where questionnaires are used and the

⁵ R. Worthington. Clinical Issues on Consent: Some Philosophical Concerns. *Journal of Medical Ethics* 2002; 28: 377–380.

participant, by willingly accepting to fill in the questionnaire and returning it to the investigator, ipso facto demonstrates having consented to participate in the research.

The professional nature of the relationship entered into by the investigators and participants and the interaction between the parties makes informed consent a process that involves the satisfaction of the three steps mentioned above. The process begins with the initial contact that an investigator makes with the prospective participants and it continues until the study is completed. The procurement of consent does not terminate with the signing of consent forms. If other factors or new information that may affect the already procured consent emerge in the course of an ongoing trial, the participants who already consented to the trial must be informed of such factors or new information. The participants' consent must be revisited in view of such intervening factors or new information. The preferred mode of recording consent is in writing. If the same cannot be obtained in writing, then this fact must be formally documented and witnessed. DoH Guidelines, Paragraph 1.2H, deals with this issue.

WHAT ARE THE ELEMENTS OF INFORMED CONSENT?

Four basic elements of informed consent have been developed since the Nuremberg trials:

- a) Capacity to consent;
- b) Full disclosure of relevant information;
- c) Adequate comprehension of the information by the participant;
- d) Voluntary decision to participate and withdraw from participation at any stage without prejudice to the participant. Participant withdrawal should be accepted and withdrawing participants should not be expected to give any reasons for their decision.

The following basic requirements are pertinent in ensuring that the four elements are present and that consent is procured in an ethically acceptable manner:

Capacity to consent

Consent must be given by a person who is legally and factually capable of consenting (MRC Guidelines, Paragraph 5.3.1). Legal capacity refers to the age of majority (eighteen years per Section 28(3) of the Constitution). A prospective participant may be

legally capable of giving consent by virtue of being eighteen years and above but this capacity may be limited by other intervening factors. The absence of such factors is referred to in this Module as factual capacity. Factual capacity should be considered alongside legal capacity because consent may be diminished on account of age, physical or mental condition.

Disclosure of relevant information

The participants must be informed that the study involves research. The purpose of the research, the expected duration of participation and planned follow up period, foreseeable risks and benefits, and available alternative procedures or courses of treatment that might be advantageous, must all be explained in a language that the consenting participants best understand. The participants must also be furnished with the contact details of the responsible person who they may contact for any required further information about research, ethical issues and welfare, or in case of injuries during the trial. A description of the extent to which confidentiality regarding identity of participants and research records will be maintained during the trial must be given to the participants.

The *Declaration of Helsinki* requires the following information to be disclosed:

- The study's aims and methods;
- Sources of funding and possible conflicts of interest;
- The researcher's institutional affiliations;
- Anticipated benefits and potential risks and the follow-up of the study;
- Discomfort that trial participation may entail;
- Right to abstain from taking part in the study, or withdraw from it at any time without any reprisals.

CIOMS Guidelines specify the requirements for prospective participants and the obligations of sponsors and investigators. The guidelines are more detailed than the *Declaration of Helsinki* because they are designed to assist countries in defining national policies on the ethics of biomedical research involving human participants within each country's local context.

Comprehension

The prospective participant must be competent to comprehend the information. Such a participant's capacity should not be

limited by virtue of being a minor, unconscious, intoxicated, grossly psychotic, or senile. Ascertaining comprehension is not easy, especially when lay people are confronted with complex medical and scientific information. Besides, it is not an easy task for an investigator to ascertain how a prospective participant interprets the provided information. The most appropriate means of determining whether the participant understands the provided information is to give such a participant an opportunity to ask questions, which the investigator should answer honestly, promptly, and completely. This ensures that there is no therapeutic misconception on the part of the participant, who may be misled into believing that every aspect of the trial is designed to be of direct benefit to him/her.

Voluntary decision

Consent must be freely in order for it to be genuine. Inducements may impair voluntariness. The issue of financial benefits or compensation, if appropriate, should be discussed after consent has been procured so that it does not form the basis on which the participant decides to give consent.

Intimidation and undue influence are factors that may invalidate informed consent. Prospective participants who have been receiving therapeutic attention from the recruiting physician must be assured by such physician/investigator that their free decision whether or not to participate in the trial will not prejudice the therapeutic relationship between them. It may be advisable in such situations for the ethics review committee to consider whether a third party, who is not party to the therapeutic relationship, procures consent instead of the physician. Factors such as unjustifiable assurances about the benefits, risks or inconveniences of research may not be acceptable as these may lead to therapeutic misconception. Neither is it acceptable to induce a close relative or a community leader of the prospective participant to influence such a participant's decision. (CIOMS Guideline 4 and Commentary on Guideline 6.)

WHAT ARE THE TYPICAL HINDRANCES FOR ACHIEVING A GENUINE INFORMED CONSENT?

What constitutes hindrances to genuine informed consent is subject to heated debates. Such debates emanate from situations that give rise to conflict between the interests of the participants and the interests of science and society.

Most prospective participants in South Africa are illiterate and poor. The following hindrances are thus prevalent in the country:

- Lack of understanding/comprehension of research details and methods: care should be taken when recruiting participants from poor backgrounds to ensure that information is conveyed to them in a language and manner that they best understand. E.g., instead of informing the participants that certain millilitres of blood samples may be drawn from them, the amount should be described in terms of the number of table/teaspoons. DoH Guidelines (Paragraph 3.5) require both written and verbal informed consent. Verbal consent, where the participant is illiterate, should be obtained in the presence of, and countersigned by, a literate witness. The DoH Guidelines (Paragraph 1.2H) requires that information be provided in a clear and simple style.
- Poverty may undermine voluntariness if the prospective participants' only way of getting medical attention is through trial participation. The description of risks and benefits of participation should be realistic, so that the prospective participants appreciate both aspects.
- Most people have an unquestioning attitude towards those in authority. They may accept whatever the recruiting physician or investigator proposes without questioning any aspects that may be unclear or unacceptable. The situation may occasion role confusion. The recruiting physician who is also an investigator should clarify to the prospective participants who are his/her patients that such patients are free to refuse trial participation without prejudice to their medical care. This ensures that there is no role confusion.

At the international level there are six major hindrances to genuine informed consent:

- Confusion and forgetfulness: some lay people may have difficulties in remembering and understanding details relating to scientific design and treatment comparisons. This may lead to the participants consenting without appreciating the risks of participation.⁶
- Cultural barriers: these may include presumed differences in the construction of personhood, language differences, and economic power.⁷

⁶ B. Cassileth, R. Zupkis, K. Sutton-Smith & V. March. Informed Consent – Why are its Goals Imperfectly Realised? *NEJM* 1980; 302: 896–900.

⁷ B. Schoepf. Ethical, Methodological and Political Issues of AIDS Research in Central Africa. *Social Science and Medicine* 1991; 33: 749–763.

- Psychological forgetfulness by participants in respect of threatening or undesirable information especially related to risk.⁸
- Situational pressure on the volunteers may be occasioned when they are involved in several procedures with different people. This may lead the volunteers to feel obliged to participate in the trial and they may also feel unable to exercise their right to withdraw from the trial.⁹
- Implicit forms of coercion such as the manner in which trial benefits are presented may threaten the participants' voluntariness.¹⁰
- Procurement of informed consent may pose challenges to the healthcare professionals' assumed beneficence, thus leading to some resistance.¹¹

Informed consent in minors and individuals unable to give consent (unconscious, mental disability, trauma etc)

Prospective participants who are minors or have mental disabilities, or are unconscious, are generally considered to be vulnerable. Capacity may be diminished as a result of coercion in the refusal process and the acceptance process. Most ethics guidelines pay special attention to such vulnerability. A prospective participant may also be vulnerable due to language barrier or an inability to comprehend modern medical concepts. DoH Guidelines (Paragraph 2.3) specifically deal with these special cases.

A minor is any person below the age of majority. Minors are legally incapable of giving consent but the ethical requirement to procure informed consent still applies in their case. The consent procedure in this regard is modified such that in all cases, assent from the minor and permission from the parent or legal guardian must be sought (DoH Guidelines, Paragraph 2.3.1). Consent can be procured from a parent or a legal guardian in respect of minors who lack the competence to make a decision about being involved in research. For minors who have the competence to

⁸ F. Verheggen & F. van Wijmen. Informed Consent in Clinical Trials. *Health Policy* 1996; 36: 131–153.

⁹ A. Meisel & L. Roth. Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies. *University of Arizona College of Law* 1983; 25: 265–346.

¹⁰ Q. Abdool Karim, S. Abdool Karim, H. Coovadia & M. Susser. Informed Consent for HIV Testing in a South African Hospital: Is it Truly Informed and Truly Voluntary? *American Journal of Public Health* 1998; 88: 357.

¹¹ A. Meisel & M. Kuczewski. Legal and Ethical Myths about Informed Consent. *Archives of Internal Medicine* 1996; 156: 2521–2526.

make such decisions, their assent and co-operation is necessary for the proposed research. The concept of competent minors is explained in the Child Care Act, No 74 of 1983. Section 39(4) provides that minors who have attained the age of 14 years are legally capable of consenting to medical treatment. Minors who have attained this age are considered competent. The consent of a parent or legal guardian is required for treatment if the minor is under the age of 14 years, and for an operation if the minor is under the age of 18 years. The child's best interests must be considered when consent is procured from parents or guardians. The MRC *General Principles* confirm that such minors' competence to consent accordingly extends to health research that is tantamount to treatment or an operation and, hence, to therapeutic research only.

The distinction drawn in the foregoing explanation is that a competent minor who is capable of making an appropriate decision about trial participation may, however, lack the legal capacity to give consent, thus an adult (parent or legal guardian) consents on behalf of such a minor. However, the minor should be provided with the requisite information and his/her assent should be sought. Such assent is not necessary in the case of a minor who is not competent enough to comprehend the information and make a decision about trial participation.

DoH Guidelines do not deal with special cases such as trials involving minors who have no parents or guardians, such as street children. The established practice in most jurisdictions is that a designated ethics review committee approves that an investigator or caregiver makes an appropriate judgement regarding whether it is in the best interest of such minors to participate in the trial. The committee has to satisfy itself that the assessment of the safety issues for the minors or the possibility of obtaining parental/guardian consent are considered before the investigator makes a decision concerning the minors' best interest. It is also safe to involve a social worker in such situations. The role of the social worker in this case is to confirm that the minors' best interests are taken care of and that the decision to include the minors in the trial is not based on the investigator's convenience.

Adults with diminished capacity e.g., mental or substance abuse related disorders, cannot consent to trial participation. The reason is that they lack capacity for reason regarding participation and comprehension of the information provided. The DoH Guidelines (Paragraph 2.3.7) describe people with mental disabilities as 'those people with psychiatric, cognitive, or developmental disorders.' People with substance abuse related disorders

may be grouped into this category only insofar as their cognitive power is impaired to the extent that they are unable to appreciate the information provided related to trial participation. They cannot generally be treated as other mentally incapacitated participants because they may have their lucid moments during which they are capable of giving valid informed consent. The determination of capacity among such participants should be assessed on a case-by-case basis. The DoH Guidelines provide for the following mandatory special considerations with regard to research involving people with cognitive disabilities or substance abuse related disorders.

The study must:

- 'Be relevant to mental disabilities or substance abuse related disorders so that it is necessary to involve people who are mentally disabled or with substance abuse related disorders.
 - Provide sufficient justification for involving people with mental disabilities or substance abuse related disorders who are institutionalised as the study population.
 - Ensure appropriate evaluation procedures for ascertaining participants' ability to give informed consent. If participants are deemed unable to understand and to make a choice, then an appropriate individual, able to consent on their behalf must be sought.
 - Ensure that consent is free from coercion and risk to patients.
 - Ensure that no more than minimal risk is involved, or if minimal risk is involved, the risk is outweighed by the anticipated benefits of the study for the participants and the importance of the knowledge which will emanate from the research.'
- (DoH Guidelines, Paragraph 2.3.7)

The Mental Health Act, No 18 of 1973 is equally relevant for research involving mentally disabled participants. Section 60A provides that where a mentally ill patient is incapable of consenting to medical treatment or to an operation, the following persons, in order of precedence, may give written consent to the treatment or operation: a curator, the patient's spouse, a parent, a major child, or a brother or sister. In the absence of such persons, or where they cannot be found after reasonable inquiry, the superintendent of the hospital where the patient finds himself may give written consent. The superintendent must be convinced, on reasonable grounds, that the patient's life is in danger, or that the patient's health is being seriously threatened by his or her condition, and that the treatment or operation in question is necessary. Ethics review committees must ensure that the proposed

trial shall yield direct benefits to such a group of prospective participants.

The Act does not deal with consent to medical treatment or operation on mentally ill patients who are not institutionalised, but are in private care and have neither curators nor relatives to consent on their behalf. In such cases, an application can be made to the High Court for the appointment of a curator. (MRC *General Principles*, Paragraph 5.3.1.1.1.)

The foregoing provision applies in a clinical practice context. For purposes of therapeutic research on mentally ill/defective (incapacitated) patients who are incapable of consenting, the MRC *General Principles* provide that proxy consent is permissible only where the proposed research pertains, directly or indirectly, to the mental illness or mental defect from which the patients suffer. In addition, the patient's assent should be obtained, provided that the patient is mentally able to comprehend the issues involved (Paragraph 5.3.1.1.1). Non-therapeutic research on such incapacitated persons is not permissible, but in exceptional cases proxy consent may be obtained for observation research of a non-therapeutic and non-invasive nature, which involves no risk and no interference with the integrity of the incapacitated person, provided that the research entails no more than negligible distress or discomfort to the incapacitated person.

In cases of unconscious prospective participants in emergency situations, the participants' best interests should be considered. What constitutes 'best interests' in this regard may be discerned from properly executed advance directives such as a living Will or durable power of Attorney. The living Will consists of two substantive parts: the declaratory statement stating the kind of procedures that the declaring party may accept or reject, and a declaration of the specific individuals in order of preference who may act as surrogates.

The durable power of Attorney for healthcare decisions is a legal document in which the person named (the donee) acts at anytime when the donor of the power of attorney is incapable of decision-making, regardless of diagnosis or prognosis. The donee does not have to be a relative of the donor and stands ahead of anyone else on the list when the durable power of Attorney is properly done.

Research protocols that are designed to address conditions occurring suddenly and rendering the prospective participants incapable of giving informed consent, such as head trauma, cardiopulmonary arrest and stroke, present unique concerns. In such studies, the investigation cannot be done with patients who

can give timely consent as it is often necessary to proceed with the intervention very soon after the outset of the condition and there may not be time to locate a person who is duly authorised to consent on their behalf. The following measures are recommended:

- As this class of emergency exception can be anticipated, the researcher must secure the review and approval of an ethics review committee before initiating the study.
- If possible, an attempt should be made to identify a population that is likely to develop the condition to be studied especially if the condition is one that recurs periodically in individuals. The prospective participants can then be contacted in advance and invited to consent to their involvement during future periods of incapacitation.
- If the prospective participants are patients of an independent physician who is also a physician-researcher, the physician should seek his patients' consent while they are fully capable of informed consent.
- In all cases in which approved research has begun without prior consent of patients/subjects incapable of giving informed consent because of suddenly occurring conditions, they should be given all relevant information as soon as they are in a state to receive it, and their consent to continued participation should be obtained as soon as is reasonably possible.
- Before proceeding without prior informed consent, the investigator must make reasonable efforts to locate an individual who has the authority to give permission on behalf of an incapacitated patient. If such a person can be located and refuses to give permission, the patient may not be enrolled as a subject.
- The researcher and the ethical review committee should agree to a maximum time of involvement of an individual without obtaining either the individual's informed consent or authorisation according to the applicable legal system if the person is not able to give consent.
- If by that time the researcher has not obtained either consent or permission – owing either to a failure to contact a representative or to a refusal of either the patient or the person or body authorised to give permission – the participation of the patient as a subject must be discontinued.
- The patient or the person or body providing authorisation should be offered an opportunity to forbid the use of data derived from participation of the patient as a subject without consent or permission. (Commentary on CIOMS Guideline 6.)

COMMUNITY VS. FIRST PERSON VOLUNTARY INFORMED CONSENT

It is at times erroneously assumed that collectivist cultures in parts of Africa and Asia place little value on personal autonomy such that proxy consent of local authorities, leaders and government officials replaces first person consent of individual community members. This is not the correct position, insofar as anthropological literature on the differences between societies characterised by collectivist and individualist values does not support the conclusion that collectivist societies unconditionally reject individuality.¹² As there is no guarantee that such proxy authorities have the best interest of all potential participants at heart, first person voluntary consent must be obtained.

For purposes of respecting the local customs and expectations of the communities from where participants are drawn, it is polite to contact local authorities and seek their authorisation and co-operation before approaching individual participants. The relevant authorities' authorisation in this regard enables the recruiting investigator to approach potential participants who must in turn give personal informed consent, which cannot be substituted by the community leader's approval of recruitment. Individual participants should similarly feel free to discuss the issue of participation with their family members, spouses and friends due to possible effects of such participation on their personal relationships, but this does not take away their autonomy to give consent personally.¹³ Adherence to local customs and expectations is an important aspect of informed consent, which should not be overlooked, not only in Africa but in any community.

There are, however, studies that by their very nature may present risks to the interests of communities, societies, or racially or ethnically defined groups. These include research in fields such as epidemiology, genetics, or sociology. The information obtained from these studies, if published, may stigmatise or expose the community members to discrimination. The information may, for example, give the right or wrong impression that the group has a high prevalence for sexually transmitted diseases or susceptibility to certain genetic disorders. These eventualities should be taken care of by maintaining confidentiality during and

¹² C. Ijsselmuiden & R. Faden. Research and Informed Consent in Africa – Another Look. *NEJM* 1992; 326: 830–834.

¹³ L. Gostin. Informed Consent, Cultural Sensitivity and Respect for Persons. *JAMA* 1995; 274: 844–845.

after the study. If the data has to be published, this should be done in a manner that respects the interests of all concerned parties. The ethics review committee should ensure that the interests of all concerned are given due consideration, and that it is advisable to have individual consent supplemented by community consultation. (Commentary on CIOMS Guideline 8.)

It should be noted that medical records and specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethics review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality, or anonymity is assured and that the research is designed to answer an important question and it would be impracticable if the requirement for informed consent were to be imposed. (Commentary on CIOMS Guideline 4.)

CASES FOR DISCUSSION

The cases are hypothetical but are based on real events.

Protocol I – pharmacokinetic trials

(Adapted from the Somerset Hospital-Cape town trial. Source: <http://www.aids-update.org.za/hiv2.HTM> – accessed on 21st July 2003)

Background

On-going patient screening is carried out at an HIV Research Unit based at hospital S to find subjects to participate in pharmacokinetic trials. The screening process entails 5 stages:

- Taking of medical history;
- Stage of HIV/AIDS is identified;
- Safety laboratory test is completed;
- HIV viral load (amount of HIV in the blood) is established;
- CD4 count is taken (T-cells/immune system cells that fight infection).

Qualification Requirements

The physicians who have been attending to the patients in the course of therapeutic care will carry out recruitment and procure their patients' informed consent. The patients must comply with the following criteria:

- New nucleoside drugs;
- Requires hospital admission;
- CD4 count more than 200;
- Viral load 5 000–100 000 cop/ml (the result of a viral load test is described as the number of ‘copies’ of HIV RNA per millilitre (cop/ml));
- Drug naïve;
- Will be eligible for follow-up study of 4–5 drug combination.

The participants will be admitted to the ward for a period of two weeks. They will receive an experimental drug or experimental combination of therapies. Regular investigations will be carried out during each trial to ascertain the safety and efficacy of the therapies being tested.

During the Trial

Patients stay in a 28-bed ward during the course of the trial. Because the patients are not allowed to leave the ward during this period, the ward is geared to keeping patients as comfortable as possible. There is a recreational area where patients can watch DSTV, play table tennis or pool, or listen to CDs. Patients are allowed to receive telephone calls, but can only make local calls from the ward. Following their discharge from the pharmacokinetic unit, patients participate in roll-over studies at the HIV/AIDS clinic which runs from hospital S.

What is Expected of Patients

Patients are expected to keep the HIV Research Unit informed of any medical events e.g., if any medication has been taken etc. Compliance is an important aspect of each drug trial.

Questions

1. Is the recruitment method ethically acceptable?
2. Are the incentives that are offered to the participants acceptable?

Protocol II – HIV study and influences on surgical ICU patients

(The Natal HIV study and the *BMJ* debate: *BMJ* 1997; 314: 1077–84.)

Background

A group from the faculty of medicine of university of N would like to investigate whether HIV status influences the outcome of patients admitted to a surgical intensive care unit (ICU) for diseases unrelated to HIV.

Highlights of the Protocol

- All patients admitted to the surgical ICU over a six-month period will be included in the trial without their knowledge or consent.
- HIV tests are to be done, but both staff and patients are blinded to the results.
- At the time of the discharge, patients may be offered the option of being advised of the results.

Questions

1. Should the protocol be accepted or rejected?
2. What are the relevant ethical issues?

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