

National Advisory Committee on Drugs

Research Ethics – Guidelines on Good Research Practice

The NACD wishes to ensure that any research study it commissions or grant aids which involves human participants is conducted so that the dignity, rights, safety and well-being of research participants are of primary consideration.

Contracts issued by the NACD state that it is the duty of the contracted consultant (and his/her employees, servants and agents) to act at all times in accordance with best practice in the area of research and to observe all appropriate ethical standards, having regard to the different ethical codes that prevail in the various areas relevant to the research to be carried out by the Consultant.

However, in the interests of promoting best practice in the field of drugs research, the NACD will require consultants to address ethical issues with the Research Advisory Group appointed to their study, and to develop a written ethics policy (following the actions outlined below) which should be followed throughout the research study.

The three areas which Consultants are required to address are:- Consent; Confidentiality; and Health and Safety risks.

A) Consent

All studies must have appropriate arrangements for obtaining consent from the research participants. It is the responsibility of the researchers to explain as fully as possible, and in terms meaningful to the potential participant, what the research is about in order to ensure that they are fully informed before deciding whether or not to join a study.

Research participants should be made aware of their right to refuse participation or withdraw from the study whenever and for whatever reason they wish and without prejudice.

Particular care is needed when research involves minors i.e. those under the age of 16. In this case the consent of parents/guardians must be sought.

In some situations, access to a research setting is gained via a 'gatekeeper'. In such cases, researchers must obtain informed consent both from the 'gatekeeper' and directly from the research participants to whom access is required.

Where a payment is made to the research participant, consent forms should state the amount being paid and act as a receipt for the payment.

Actions

1. Develop a Research Information Leaflet (see sample attached) outlining the aims of the research, contact details of the researcher etc. for distribution to participants.
2. Develop a copy of the Consent Form to be used (see sample attached) to be signed by participants and, where applicable, their parent.

B) Confidentiality

Researchers are responsible for protecting the integrity and confidentiality of records and data generated by the research. Guarantees of confidentiality and anonymity must be honoured, unless there are exceptional, clear and overriding reasons to do otherwise such as a court order. All members of the research team and others who may have access to the data must be made aware of their obligations in this respect.

Anonymised data i.e. data which does not identify the person to whom it relates, should be used wherever feasible.

Appropriate measures should be taken to store research data (both hard copy and computer data) in a secure manner and, where applicable, in accordance with the provisions of the Data Protection Act. These may include the removal of identifiers, the use of pseudonyms and other technical means for breaking the link between data and identifiable individuals.

Extreme care should be taken when delivering or transferring any confidential material over computer networks.

Care should also be taken to prevent data being published or released in a form that would permit the actual or potential identification of research participants.

Arrangements must be made for the appropriate archiving or destruction of data when the research study is completed.

Actions

5. Develop written policy on how research data (both hard copy and computer) will be stored so as maximum protection is afforded to the respondents.
6. Register project under the Data Protection Act (1998) if required.
7. Develop policy for dealing with data records at the conclusion of the research study.

C) Health and Safety Risks

Field work conducted in drugs research studies brings the researcher into contact with people and situations where illegal activities, such as the sale and use of illicit drugs, are taking place which may have health and safety implications for the field workers.

Researchers should ensure that research participants are not unnecessarily identified or exposed as drug users because of their participation in the research and that interviews are held in private areas.

Actions

8. An assessment of any potential risks to the field workers and participants should be conducted and precautions taken to minimise these risks.

Aileen O’Gorman, Research Officer, NACD - 2/10//02

Researcher's Name:

(use block capitals)

Organisation (Name and Contact details):

Title of Study:

Outline of research study

Guarantee of confidentiality

The researcher declares that every possible effort will be made to securely and safely store the information given by the respondent and to refrain from disclosing its contents to any unauthorised personnel.

SAMPLE CONSENT FORM

Researcher's Name:
Organisation:
Title of Study:
<p>Consent (To be completed by the participant/parent/guardian – delete as necessary)</p> <p>1. Have you been fully informed/read the information sheet about this study? YES/NO</p> <p>2. Have you had an opportunity to ask questions and discuss this study? YES/NO</p> <p>3. Have you received satisfactory answers to all your questions? YES/NO</p> <p>4. Do you understand that you are free to withdraw from this study?</p> <ul style="list-style-type: none"> • at any time • without giving a reason for withdrawing • without your withdrawal having an adverse effect for you. YES/NO <p>5. Do you agree to take part in this study the results of which are likely to be published? YES/NO</p> <p>6. Have you been informed that a copy of this consent form will be kept by the researcher? YES/NO</p> <p>7. Are you satisfied that any information you give to the researcher will be kept confidential. YES/NO</p>
<p>Name of Participant (printed) _____</p> <p>(signature)_____ Date _____</p> <p>Name of Parent/guardian, if applicable (printed) _____</p> <p>(signature)_____ Date _____</p>
<p>Signature of Researcher _____ Date_____</p>