GUIDELINES FOR SUBMITTING RESEARCH PROPOSAL FOR ETHICAL REVIEW

INTRODUCTION

Researchers (academics, scientists, students) have the responsibility to adhere to the highest ethical and scientific standards in formulating, conducting and presenting research. Researchers/investigators have the responsibility to:

- Ensure that the welfare of human subjects participating in research is safeguarded.

- Respect all ethical principles in research, including:
    a. The research participants' rights to privacy and confidentiality of research and information
    b. The right of subjects to information on experimental procedures
    c. Participants' psychological well-being
    d. Respect for participants' social stability

CONFIDENTIALITY

Confidentiality imposes the duty on researchers/ investigators effectively securing any access to participants' personal information. Records that may identify participants must be kept safe and confidential, and should not be made publicly available unless so required by local laws or regulations. Confidential information must not be released without the participants' consent.

CATEGORY OF RESEARCH PROTOCOL

1. Studies with MINIMAL risk where the objective is an increase in knowledge WITHOUT there being any benefit to the participating subject.

GUIDELINES FOR PREPARING RESEARCH PROTOCOLS

Research protocols should be submitted to the Medical Officer or Health in the parish where the proposed research is to be conducted, for evaluation of the ethical and scientific merits. Where the site of the proposed research includes a hospital, the Senior Medical Officer of the facility should also receive a copy of the research protocol, and his/her approval to conduct the study should be obtained. The following information will be required for the consideration of research proposals.

1. TITLE OF THE PROPOSED RESEARCH

2. DATE

3. NAME AND ADDRESS OF ALL THE INVESTIGATORS, COLLABORATORS, AND/OR SUPERVISORS (starting with the principal investigator). Indicate which parts of the protocols each investigator will be responsible for. Who will actually carry out any procedure participants, and if appropriate, what training they have had. *(this could be limited to identifying the groupings, for example, technical advisors, coordinators, facilitators, data entry personnel, data analyst) We could also include OAS/CICAD as institutional collaborators.*

4. SITE (S) OF RESEACH (provide generic information to indicate that school will be selected randomly and from experience about how many school are likely to be included). The respondents will complete a self administered questionnaire during a regular school session/lesson period in their classroom.

5. NUMBER OF SUBJECTS TO BE ENROLLED (approximately how many students are likely to be included – this from past experience)

6. PROPOSED DURATION OF STUDY

7. A SUMMARY OF THE PROPOSED STUDY/ THE PROJECT PROPOSAL – (see generic text)

Introduction

As a general guideline, it consists of a study coordinated with the Inter-American Drug Abuse Commission (CICAD) with the following characteristic: standardized questionnaire drawn up by the Inter-American Uniform Drug Use Data System (SIDUC). Every country participating in the survey adapts the questionnaire to its local language and conducts the pilot testing for its final adoption.

The country is in charge of:

- ***Preparing the sampling frame.***
- ***Designing and selecting the sample.***
- ***Organizing data gathering, including choosing and training the interviewers or facilitators.***
- ***Gathering and entering the data.***
- ***Processing and analyzing the data.***
- ***Reporting the results.***
- ***Editing and publishing the written and online reports.***

It is expected that this study will have nationwide coverage applying the instrument in schools selected by sampling and encompassing the population of both genders, from 13 to 18 years of age, from both public and private schools.
In short, in its descriptive part, this survey is aimed at learning, among other statistical data, about the various values of the prevalence of psychoactive substance use in the secondary school population, in other words: the number of students using Psychoactive Substances/total number of students, without neglecting the establishment of certain possible linkages that would make it possible to provide an initial explanatory value of this phenomenon.

Objectives:

- ***The main objective of this study is to determine the prevalence, perception pattern (trend) and age of first use of drugs consumption among the secondary students throughout COUNTRY X.***
- ***To provide a tool for policy and decision makers at the national level to combat the drug problem related to the human and financial costs within COUNTRY X.***
- ***To generate statistics for stake- holding agencies***
- ***To provide statistics for making recommendations for future policy – orientation***
- ***To provide information to both demand and supply reduction section in an effort to guide program planning.***

Description:

The _____ Unit will be the executing agency responsible for implementing this study. Assistance will be sought through the Ministry of Education and the Statistical Division. Prior to the field work, the coordinator tasks will include:

Seeking permission from the Permanent Secretary responsible for Ministry of Education and the principals of the various secondary schools requesting authorization to conduct the study and giving objectives of the study.

Seeking permission from parents/ guardians for their child(ren) to participate in this study and outlining its importance.

- ***Organize all details of the study***

- ***Work in accordance with an established timetable***

- ***Conduct training for facilitators, to verify the same understanding of the questions in the survey. Also to clear any ambiguity that may arise from the questionnaire to ensure that the facilitators are able to answer student's questions.***

Methodology:

A study of drug prevalence of secondary and tertiary school students with COUNTRY X will be conducted. All students of 2nd, 4th 5th, and 6th forms from private, public and mixed schools throughout COUNTRY X will be targeted. The data collected will take approximately one to two week.

A self-administered questionnaire comprised of XX questions on illicit and licit drug use, knowledge, beliefs and perception of the consequences of use, and curiosity towards use of these drugs will be administered. The Inter- American Uniform Drug Use System (SIDUC), the standardized Questionnaire for Secondary Schools will be used.

Expected Results:

The expected results of this proposed study will:

- ***Assist the Government of COUNTRY X in the development of appropriate policies to effectively address the problem of drug use/ abuse in the secondary schools.***
- ***Be used for the implementation of education drug prevention programmes with the secondary schools.***
- ***A valuable tool for the _____ Unit in the creation of appropriate student assistance programme –based counseling, treatment and rehabilitation programmes.***

(A copy of the questionnaires to be administered should be attached)

All abbreviations should be explained

8. FAIR SELECTION OF SUBJECTS

A statement affirming that subjects were selected only because of the specific problem under investigation, and not because of their easy availability, diminished autonomy, or due to social bias.

9. COPY OF THE INFORMED CONSENT FORM (A generic example will be posted on the webpage for adoption).

This must include:

- Statements outlining in lay language the purpose of the research, what will be done in the study, and indicating that this has been explained orally and in writing to the participant (or the participant's parent or legal guarding if a child) who understands at will be done. These must be countersigned by participant or his/her legally authorized representative;

- A statement that the subject's participation is voluntary, and that refusal to participate, or (if after having agreed to participate) withdrawal from the study at any time not affect the participant's access to care or affect the type of care to which she/he is entitled;

- The name, address, telephone and fax numbers, and e-mail address, if any, of a contact person;

- A statement confirming that time was given for the participant to consider his/her involvement;

- Statement that the participant or his/her legal guardian has read the informed consent form or that it has been read to him/her. And that she/he understands its content; that a copy will be given to the participant; and that the signature of the participant or the legal guardian indicated that she/he has freely agreed to participate;