

## Ethical Guidelines for Approval to Undertake Projects

### General Information

1. The Spastic Centre requires investigators to conform to the Guidelines for Human Experimentation of the National Health and Medical Research Council (NH&MRC) under the terms of the Helsinki Declarations to which the Australian Government is a signatory. All projects involving human subjects are to be conducted in conformity with NH&MRC Guidelines (NH&MRC Statement on Human Experimentation and Supplementary Notes, 1985, and amendments thereto) – copy attached. Note that the Guidelines refer not only to the physical and mental wellbeing of participants/subjects, but also to matters of confidentiality, privacy and consent.
  
2. The Spastic Centre has established a Committee to review the ethical aspects of procedures where humans participate as subjects in research or investigative projects. This Committee, known as the Spastic Centre Ethics Review Committee, is directly responsible to the Chief Executive Officer.
  
3. All projects which involve –
  - the use of questionnaire to obtain any form of personal information<sup>1</sup>
  - access to medical or other personal records
  - investigations of human behaviour
  - routine testing of human subjects
  - administration of drugs, chemical agents or vaccines
  - a clinical trial (testing a drug, a surgical or other procedure or diagnostic device)
  - other experimentation on human beings require the approval of an Ethics Committee.
  
4. Before carrying out any project with human subjects, staff are required to submit an Application for Ethical Approval, using the attached form. 7 copies, stapled in top left corner, must be submitted to the Ethics Committee Secretary located at The Spastic Centre's Head Office, 189 Allambie Rd, Allambie Heights, NSW 2100.

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<sup>1</sup> Please note that this does not apply to normal personnel practice which is governed by common law and statute laws.

## **General Ethical Guidelines for Studies Involving Human Subjects**

### **1. Responsibility of the Investigator**

In planning a study using human subjects, the researcher must undertake a careful evaluation of the ethical issues involved. Whatever guidance is sought from others, the responsibility for ensuring ethical practice in research remains with the principal investigator and cannot be shared. It is the responsibility of the investigator to ensure that the study is conducted in such a manner that the welfare of the subjects is not compromised, and that the study conforms with the NH&MRC Statement on Human Experimentation and Supplementary Notes 1985, and amendments thereto.

### **2. Investigations Involving Invasive Procedures, Physical or Mental Stress**

When the study necessarily involves subjects in invasive procedures or physical or mental stress, the investigator must conscientiously inform the subjects of the procedures to be used, and the physical and/or psychological effects to be expected.

No procedures likely to cause severe pain or distress should be used under any circumstances. If unexpected pain or stress reactions do occur, the investigator has the responsibility to immediately alleviate such reactions and to terminate the study.

It is incumbent upon the investigator to give special consideration to safeguard physically or psychologically handicapped persons who may participate in the project. This applies particularly to persons who are institutionalised (such as the mentally ill). Other specific examples may be found in the NH&MRC Statement on Human Experimentation, supplementary note 2.

### **3. Risk of Injury**

The investigator must take all reasonable steps to ensure that the subject is not exposed to accidental injury (eg: from faulty equipment or poor experimental design).

### **4. Consent**

The investigator should inform each participant, in a form readily intelligible to him or her, of the nature of the study. After ensuring that the participants understand the information and that the consent to participate is voluntary, consent should be obtained in writing.

Participants should be advised that they may withdraw from the study at any time. If informed consent cannot be obtained – by reason, for example, of the stage of intellectual development of the participants – consent must be obtained from the persons who are legally responsible for the subject's welfare.

An investigator must not use a position of authority to exert undue pressure on potential subjects for the purpose of securing their participation in a particular study.

## **5. Confidentiality and Privacy**

In the conduct of the study, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subjects.

Test results or other confidential data obtained in a study must never be disclosed in situations or circumstances which might lead to identification of the subjects unless their permission has first been obtained. Steps should also be taken, wherever possible, to ensure that the procedures for establishing confidentiality are explained to subjects at the outset of the research.

## **Explanatory Notes in Relation to the Application Form (Attachment 9)**

The Application Form sets out a number of questions which are intended to raise some of the ethical issues which commonly arise. It is not intended to create a system which might inhibit research, but rather to ensure that the ethical implications are being given serious consideration before the project begins. You are accordingly requested to answer the questions in the Application Form. Please answer in terms that are readily intelligible to individuals not specialist in the subject, avoiding highly specialised expressions and acronyms.

### **Section 1**

Choose a title, which will direct the Committee's attention to the essential point of the project, preferably in simple, non-technical terms. While a formal research title aimed at colleagues might be, eg: "Differential efficacy evaluation of Ketotifen regimen against standardised and anti-histamine regima with respect to asthma morbidity in Upper Hunter adolescent cohort", the short title might well be "Test of new anti-asthma drug" and the rest explained in the text. The short title should be used on the explanatory material and consent form. All titles should be consistent with those used on external funding application(s).

### **Section 2**

Please complete as applicable. Note that the Committee assumes that personnel listed in response to Question 2 comprise those who will be responsible ultimately for the conduct of the experiment. For example, if a technical officer is to carry out human interventions in the course of an experiment (say take blood samples), then it is assumed that the investigators will be responsible personally for ensuring that the technical officer is appropriately trained and instructed and is working with appropriate equipment in an appropriate environment, and approaches people in an appropriate manner.

### **Section 3**

The Committee needs to monitor the project. If its duration exceeds that outlined for which approval has been given, the project requires resubmission.

**Section 4**

The Committee is constituted according to the NH&MRC guidelines and includes lay people, a minister of religion, a lawyer, a medical graduate with research experience. Please make your statements clear to lay people as well as to academics unfamiliar with your field. The Committee needs to understand the essential issues involved if it is to make a proper assessment of the rationale for the particular human interventions proposed. The educational or other significance of projects intended for teaching only or teaching/research should be indicated (“other purposes”).

**Section 5**

To be scientifically valid, a study must be designed to yield reliable information, according to accepted principles and research practice. However, a study may be scientifically valid but have little scientific value. The Committee wishes to know why this particular research proposal is worth undertaking. If the results of this research were never received, would the information be missed? What special groups stand to benefit? (For example, a particular group of patients, say asthma patients, may stand to obtain an improved drug regimen in consequence). What further avenues of research will be opened up by this information?

The application may be accompanied by supporting information, as appropriate. For example, a detailed research protocol might be included.

**Section 6**

All procedures must be described, whether invasive, such as venipuncture, drug administration, laboratory tests or biopsies, or non-invasive, such as participation in questionnaires or surveys, interviews or the use of confidential medical records. Copies of any questionnaires or survey forms should be included with the application. The term “participants” on this form includes controls. If, in the course of the project, procedures vary significantly from those given on the form, the Committee must be informed in writing.

**Section 7**

Will participants run the risk of physical or psychological stress, or social ill effects in either the short or the long term? Does the project raise issues of privacy and confidentiality? In what respect do the potential benefits to the participants, or contributions to general knowledge, outweigh the risk? What safeguards have been established to ensure that the research is modified or stopped if it becomes apparent that it may be harmful? Investigators should refer to the attached NH&MRC Statement on Human Experimentation for further information.

**Section 8**

Be clear about what each individual will have to do, how long each experiment will last and how long each person will be involved.

**Section 9**

It is important to minimise the number of participants who are involved. However, too few participants may undermine the scientific value of the research through a failure to reduce measurement errors sufficiently. The Committee needs a simple statement of how these factors are to be reconciled.

**Section 10**

From what group will participants be drawn, eg: hospital patients? Will participants be recruited by advertisement, referral by the treating doctor or some other method? Why should one particular group of people be asked to participate and not another? Often a control group may need to be selected from the population at large and some experiments will require sampling the general population – in these cases, it is simply necessary to ensure that there are no unintended or unconscious biases in the sampling which might represent an unfair imposition or imputation on particular groups of people.

**Section 11**

Such special relationships may include doctor/patient, teacher/pupil, junior/senior staff, researchers/laboratory workers. Special precautions need to be taken with regard to recruitment and to obtaining informed consent if a special relationship exists.

**Section 12**

Such criteria may include age or a pre-existing health condition, such as pregnancy.

**Section 13**

The NH&MRC stipulates that volunteers may be paid for inconvenience and time spent, but that such payment should not be so large as to be an inducement to participate. The answer to Question 13 should include the reasons for payment and the timing of payment(s).

**Section 14**

Self Explanatory.

**Section 15**

If the project exposes participants to a level of risk (during and/or after the study) higher than that for day-to-day living, describe what steps are taken to minimise the risk.

**Section 16**

Research files may often contain confidential information and it is essential that the responsible researchers ensure that the information is accessible only to persons directly responsible to them. When the necessary information has been extracted from the research data, and should the data be judged to contain no longer term value, it is essential to ensure that it is destroyed by a procedure, which allows the researchers responsible for the project to attest to this fact.

**Section 17**

Self Explanatory.

**Section 18**

Self Explanatory.

**Section 19**

In many areas of research involving humans, there is a trade-off to be made between the cost of the human interventions to those participating in them (eg: in terms of discomfort, health risk, loss of privacy, etc) and the value to be achieved by carrying out the research. The Committee must be in a position to evaluate that trade-off clearly.

**Section 20**

Self Explanatory.

**Section 21**

Self Explanatory.

**Section 22**

Self Explanatory.

**Section 23**

Some participants may be incapable of giving consent due to age, mental illness or handicap, or other condition. In these cases it is essential to ensure that there is someone who may speak responsibly on behalf of the participant and to ensure that the informed consent of that responsible person is obtained. Investigators should refer to NH&MRC Supplementary Note 2.

**Section 24**

Paragraph 8 of the NH&MRC Statement of Human Experimentation says, in part, "Consent should be obtained in writing unless there are good reasons to the contrary. If consent is not obtained in writing, the circumstances under which it is obtained should be recorded".