

(PLEASE READ BEFORE COMPLETING ETHICS APPLICATION FORM)

SCHOOL OF NURSING AND MIDWIFERY RESEARCH ETHICS COMMITTEE

APPENDICES

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APPENDIX 1

Guidelines for regarding participant information leaflet

A Participant Information Leaflet must be submitted with the application based on the following outline. The leaflet should be written in clear non-technical English and aimed at the potential participants in the project, and not at members of the Research Ethics Committee.

All the areas in the following outline should be included. For several of the areas, **recommended wording is provided in italics and should be used if appropriate for the particular study.**

3. **Title of study:**
4. **Introduction:** Provide a brief description of the research project, stating the purpose of the study, the procedures involved, and the extent of the participant's involvement, e.g. time span of participation, expected number of visits to the laboratory or clinic.
5. **Procedures:** List the criteria for selection for participation in the study, e.g. that the participant has a particular complaint, is between certain ages, is not covered by the criteria for exclusion, and, if a woman, is not pregnant or likely to become pregnant. Then detail the nature of the participant's involvement, including all procedures to be undertaken.
6. **Benefits:** List any potential benefits of the study. These may include direct benefits or be related to future more general benefits as a result of knowledge gained.
7. **Risks:** List the material risks, discomforts and side effects involved in participating in the study. Material risks are those that a prudent person in the participant's position would regard as significant in considering whether or not to undergo the procedures in question. If the risks attaching to a treatment are unknown this should be stated.
8. **Exclusion from participation:** You cannot participate in this study if any of the following are true: (list the criteria excluding an individual from participating in the study).
9. **Confidentiality:**
Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.
10. **Compensation:**
This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.
11. **Voluntary Participation:** If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

12. **Stopping the study:** You understand that the investigators may withdraw your participation in the study at any time without your consent.
13. **Permission:** State that the trial has Research Ethics Committee approval from all institutions involved.
14. **Further information:** You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr.....who can be telephoned at If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

ADDITIONAL GUIDELINES FOR INFORMATION LEAFLET

Include the following points:

Names of researchers

Working title of study

Description of study

- Aims and objectives of study (what the study is about, why this population)
- Contribution required from participant (what the study involves, what the participant will be asked to do)
- Possible benefits of the study
- Possible risks to participants and after effects
- Location of research
- What will happen to the results of the study

Confidentiality of information

- How information will be stored
- How confidentiality will be ensured

Compensation

Voluntary participation

- Not obliged to take part
- May withdraw at any time

Permission

- Ethical approval from X institutions

Further information and how to take part

- Contact details of researcher

APPENDIX 2

GUIDELINES FOR INFORMED CONSENT FORM

The Informed Consent Form is a legal document in which the project must be comprehensible to a reader without reference to the Participant Information Leaflet. It must contain Project Title, names of the Principal Investigators and a summary of what will be involved for a participant. **This summary should be written in the first person since the signatory is agreeing to undertake whatever procedures are involved.**

Participants must agree that they understand what is involved in participation in the project, consent to take part on a voluntary basis and understand that they may withdraw at any time at their request or be withdrawn by the investigator without any effect on access to services or legal rights.

If appropriate, you may also wish to obtain agreement to:

- use of data in other future studies without the need for additional consent.
- access to non-anonymised patient records.
- waiver of intellectual property rights
- consent to possible publication of results

If a commercial sponsoring body is involved, you need to name the sponsor and obtain consent for a copy of the signed form to be sent to that body.

The form needs to be signed by the consenter (or a parent or guardian in the case of the participant being unable to understand the scope, nature or significance of the study or in the case of the participant being under 18 years) and dated.

The above section must be followed by a signed declaration by the researcher that s/he:

- Has explained the study.
- Has answered questions.
- Believes that the participant understands and is freely giving consent.

The researcher should retain the original of the signed form in a secure file, give one copy to the participant, and send one copy to the sponsor (if appropriate).

TEMPLATE FOR INFORMED CONSENT FORM

Please use the exact wording below for the Participant's **Declaration** of Agreement and the **Statement of Investigator's Responsibility**:

PROJECT TITLE:

PRINCIPAL INVESTIGATORS:

BACKGROUND

(provide short summary of what project involves for participants, including the procedures to be carried out and the assurance of confidentiality)

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

PARTICIPANT'S NAME:

CONTACT DETAILS:

PARTICIPANT'S SIGNATURE:

Date:.....

Where the participant is incapable of comprehending the nature, significance and scope of the consent required or is under 18 years old, the form must be signed by a person legally competent to give consent.

NAME OF CONSENTER, PARENT or GUARDIAN:.....

SIGNATURE:.....

RELATION TO PARTICIPANT:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:..... **Date:**.....

(Keep the original of this form in the investigator's file, give one copy to the participant, and send one copy to the sponsor (if there is a sponsor)).

APPENDIX 3

Guidelines for research on women of childbearing potential

The committee recognises the importance of undertaking research in diverse population groups including women of childbearing potential. However, it notes that there is a need for special care in this group because of the possible hazard to the potential fetus. In order to minimise any risk the committee requires that the following 8 questions be considered before it will give permission to perform any study involving women of childbearing potential.

CHECKLIST

1. Have you included a copy of the participant information leaflet and consent form to be given to each participant? Your application will NOT be considered unless these are included
2. Does the nature of the study justify involving women of childbearing potential?
3. Has toxicological and pharmacological testing in animals or humans, performed to date, failed to produce any evidence that the study drug may be teratogenic?
4. Is there a clear warning in the patient information sheet that the effects of the study drug on a foetus are unknown but that they may be damaging?
5. Is a pregnancy test to be performed immediately before the study begins?
6. Are the forms of contraception allowed (and those forms which are unacceptable) specifically stated in the research protocol?
7. Is there a clear indication in the patient information sheet that effective contraception must be practised during and for a time (corresponding to drug elimination kinetics) after the trial?
8. Does the study exclude any participant whom the investigators feel is unlikely or unable to follow contraceptive advice?
9. Is there a statement that if the patient becomes pregnant, or thinks she may be pregnant, that she should contact the study doctor immediately?

Where appropriate the following paragraph should be included:

If you are a woman of childbearing age, you may participate in this study only if you are surgically sterilised or are using the contraceptive pill. You must not be pregnant or lactating and you must have a negative pregnancy test before the study begins. The effects of... on the foetus or child are unknown and may be harmful. If you should become pregnant, in spite of all the precautions, please notify your doctor immediately.

APPENDIX 4

Declaration of Helsinki

The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human research includes research on identifiable human material or identifiable data

Recommendations Guiding Physicians in Biomedical Research involving Human Participants.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly, Hong Kong, September 1989.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human participants must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human participants.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may effect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human participants. They should be kept under review in the future. It must be stressed that the standards as drafted are

only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the law of their own countries.

Basic Principles

3. Biomedical research involving human participants must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
4. The design and performance of each experimental procedure involving human participants should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
5. Biomedical research involving human participants should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human participant must always rest with a medically qualified person and never rest on the subject of the research, even though the participant has given his or her consent.
6. Biomedical research involving human participants cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the participant.
7. Every biomedical research project involving human participants should be preceded by careful assessment of the predictable risks in comparison with foreseeable benefits to the participant or to others. Concern for the interests of the participant must always prevail over the interests of science and society.
8. The right of the research participant to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the participant and to minimize the impact of the study on the participant's physical and mental integrity and on the personality of the participant.
9. Physicians should abstain from engaging in research projects involving human participants unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
10. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
11. In any research on human beings, each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from

participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the participant's freely-given informed consent, preferably in writing.

12. When obtaining informed consent for the research project the physician should be particularly cautious if the participant is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
13. In the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the participant is a minor, permission from the responsible relative replaces that of the participant in accordance with national legislation.

Whenever the minor child is in fact able to give consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighted against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient – including those of a control group, if any – should be assured of the best-proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for the proposal should be stated in the experimental protocol for transmission to the independent committee (1.2).
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

Non-Therapeutic Biomedical Research involving Human Research Participants (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The participants should be volunteers – either healthy persons or patients for whom the experimental design is not related to the patient's illness.

The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

3. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the participant.

APPENDIX 5

Guidelines for storage of information

Consider carefully the documents that will bear personal information such as participant's name, address and telephone number. Often only one document e.g. the consent form will need to bear such information.

An identity number should be generated for each participant, in this way data/information will be anonymised. With the exception of the one document that contains participant's personal information all other information will be distinguished via this identity number.

Data should be handled in the following way:

1. Each researcher will store the document bearing personal information in a locked cabinet with access strictly restricted to personnel working on the study.
2. All computerised data/information will be stored in a locked cabinet, again with restricted access and pass worded.
3. The researcher responsible for the project will be the person with access to the data/information generated by the study.
4. All computerised data/information collected should be anonymised by using identity numbers for the participants.
5. The data/information will be stored for the duration of the study, i.e. until the work is fully reported and disseminated. It will then be kept in a locked cabinet for five years.

APPENDIX 6

Guidelines for projects involving performance/abilities of school children

- except with very young children, individual assent should be obtained from each child as well as formal consent from a parent/guardian
- children in second level education should give written assent except for “children” age 16 or over who may give their consent
- if study data are passed to the school they should be anonymised
- if it is seen as appropriate for remedial purposes that data on a particular identifiable child are passed to the school, this must be approved in advance by the parent/guardian
- if the investigator is a student, the decision to pass information on an identifiable child to parent/guardian or school must be made by the investigator’s supervisor