UHWI UWI FMS ETHICS COMMITTEE
UNIVERSITY OF THE WEST INDIES
MONA, JAMAICA

ETHICS PROPOSAL REQUIREMENTS

Submission of research proposals, projects, and requests

Research papers and proposals are to be submitted at least four weeks before the meeting of the committee. Requests for case review and policies may be submitted to the Chairman of the Ethics Committee or the Dean of the Faculty of Medical Sciences at any time.

Procedure to approve research projects

The following information will be required:

A. **A cover letter, addressed to the Chairman, Professor Archibald McDonald, UHWI/UWI/FMS Ethics Committee requesting Ethical review of the proposal.**

B. **SUMMARY OF THE STUDY** (not more then 250 words)
This should include:
1. The usefulness and significance of the study
2. The hypothesis and scientific basis or justification for the study
3. An outline of the study design
4. An assessment of the benefits (to participants and/or groups in the community or the entire community) and the risks
5. An indication of steps taken to ensure and maintain confidentiality
6. A statement affirming respect for, and the maximum protection of the best interests of the research subjects

C. **THE PROJECT PROPOSAL** (See Guidelines)
This should include:
1. Introduction and background information on the research topic
2. A clear statement of the Objectives of the research proposal
3. Justification for the research
4. Materials and Methods
5. Draft copy of all correspondences to be sent to entities internal and external requesting permission to access

D. **A COMPLETED CHECKLIST**

For persons conducting research at the undergraduate and graduate level, the checklist should be completed and signed by the person supervising the research

F. **INFORMED CONSENT FORM (**See informed consent form guidelines)

Undergraduate and graduate researchers must state in the form that "the research is being done in partial fulfillment of the Degree in……."

G. **ASSENT FORM** (See sample assent form)
For research participants less than 18 years old

H. **REQUIREMENTS FOR FAIR SELECTION OF SUBJECTS**

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

This ethical principle ensures that the benefits and burdens of medical research are distributed fairly (distributive justice).

All undergraduate and graduate students are encouraged to complete the online course on the Citiprogram website at: https://www.citiprogram.org/aboutus.asp?language=english in "Responsible Conduct of Research".
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INFORMED CONSENT GUIDELINES

Your informed consent form must include the following:

Title of the Study:

Purpose and description:

Statements outlining in lay language the purpose of the research.

Procedures:
A description of what will be done in the study and how long the procedure will take (eg questionnaire/interview and the timeframe for completion of procedure). If interviews will be recorded, state how the tape/manuscript will be handled once the data have been extracted

Risks:
Explicit statements about any risks or discomfort to the participant, with an assessment of the degree of risk and viable alternatives

Benefits:
Explicit statements about any benefits to the participant, or to the wider society

Right to withdraw or refusal to participate:
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 will not affect the participant's access to or the type of care to which he or she is entitled

Confidentiality:
A statement on how participant's anonymity will be maintained

Compensation:
A statement that addresses whether or not compensation will be given for participating in the study. If compensation is given, the monetary amount/incentive should be stated.

Contact Details for Researcher/Principal Investigator
The following statement must be included: "If you have any questions regarding the research project, you may contact the principal investigator; (*Name, address, e-mail address and telephone number)*".

Rights as a Research Participant:
The following statement must be included: "For independent advice on your rights as a research participant please contact Professor Archibald McDonald, Dean, Faculty of

Medical Sciences, University of the West Indies, Mona, Kgn 7 (Tel: (876) 927-1297, e-mail: medsci@uwimona.edu.jm)".

Statement of DECLARATION:

1. Statements 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 s/he understands its contents; that a copy will be given to the participant; and that the signature of the participant or the legal guardian indicates that s/he has agreed to participate;
2. that time will be given for the participant to consider his or her involvement
3. Provision of space for an independent witness (not connected to the research protocol).

Name of Respondent:_____

Signature of Respondent: _____

DATE:_____

Name of Researcher:_____

Signature of Respondent:_____

Date:_____

Signature of Independent Witness :_____

SAMPLE ASSENT FORM
FOR CHILDREN

ASSENT TO PARTICIPATE IN RESEARCH

1. My name is *{identify yourself to the child by name]*

2. We are asking you to take part in a research study because we are trying to learn more about *[outline what the study is about in language that is appropriate to the child's maturity and age]*

3. If you agree to be in this study *{describe what will take place from the child's point of view in language that is appropriate to the child's maturity and age)*

4. *[Describe any risks to the child that may result from participation in the research]*

5. *[Describe any benefits to the child from participation in the research)*

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes", you can still decide not to do this.

7. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me *[insert your telephone number)* or ask me next time.
9. Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____
Name of Child (please print)

_____ _____
Signature of Child Date

_____ _____
Signature of Investigator or Designee Date