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. Also indicate if the study is being conducted in partial fulfillment of a degree.

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)

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 Dr. Gilian Wharfe, Chair, Faculty of Medical Sciences, University of the West Indies, Mona, Kgn 7 (Tel: (876) 970-4892, e-mail: mcrec@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