THE UNIVERSITY OF THE WEST INDIES

ST. AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES

CAMPUS ETHICS COMMITTEE

Application for Prospective & Invasive Medical Research

Phone: 645-3232 Ext: 5021 Email: campusethics@sta.uwi.edu

For official use (Reference Number)

Date of Application

Complete Protocol Title

Principal Investigator

Co-Investigators

Data Analysis Collaborator(s)

Research Site(s)

Research Start Date **End Date**

Signature of Principal Investigator **Date**

Signature of Co-Investigator **Date**

INVESTIGATOR'S INFORMATION:

Principal Investigator (include degrees)

Email **Phone**

Departmental Mailing Address

Co- Investigator (include degrees)			
Email		**Phone**	
Departmental Mailing Address			
Administrative Contact			
Email		**Phone**	

PROTOCOL BACKGROUND
Will this protocol include any of the following special populations? (Special populations attract strict review)

	Yes	No
Pregnant women (drugs may affect unborn baby)	○	○
Children (subjects less than 18 years old) If YES, parental consent must be obtained since these subjects are incapable by law to provide consent	○	○
Persons with diminished mental capacity (Special situations may cause these subjects to be taken advantage of)	○	○
Prisoners (Special situations may cause these subjects to be taken advantage of)	○	○
Embryos, foetuses or abortuses	○	○
Non-English speaking subjects (Subjects must understand purpose of research and their right as research subjects.)	○	○
Would volunteers be paid?	○	○
Would you advertise to recruit subjects?	○	○

Briefly explain the rationale for the involvement of the special classes of subjects listed above including human in vitro fertilization, other institutionalized individuals or others who are likely to be vulnerable or whose ability to give voluntary consent may be in question.

1. BACKGROUND AND RATIONALE OF YOUR PROPOSED RESEARCH

A. Background of Project in brief:

B. Describe the research hypothesis or objective of your study

C. State clearly the reason for having human subjects**:**

2. FACILITIES AND PERSONNEL

A. Will human materials (e.g. blood, tissue or urine) be collected? If so, please state briefly what materials and which Laboratory will be testing these samples.

B. Will the samples be stored and if so for how long?

C. Briefly summarise the professional experience and training of the Principal Investigator to undertake this research.

3. DETAILS OF FUNDING

A. Is the research included in a grant proposal?

- ◯ Yes
- ◯ No

B. If YES, what is the proposed grant funding period and the organisation/ institution

4. SUBJECT POPULATION

Describe the characteristics of the proposed subject population:

A. List the inclusion criteria for subjects

B. List he exclusion criteria for subjects

C. Summarise the gender, racial and ethnic composition of the subject population

5. SUBJECT RECRUITMENT

A. Describe plans for the recruitment of potential subjects from available population and give the sample size

B. Estimate the samples to be approached (screened) compared to the expected number that will actually be enrolled.

C. Will dropped subjects be replaced until the appropriate sample size is obtained? If so, how?

D. Will you identify potential subjects from hospital or clinic records, logbooks, schedules, institutional database, extramural data/tissue repository or disease database? If so please mention how.

E. Will you use commercial advertisements (including the internet) to recruit subjects and if so which?

6. SOURCE OF RESEARCH MATERIAL

Explain briefly how and where research material (subjects, sample or data) will be obtained

7. PROJECT PROTOCOL

Give detailed information about your protocol answering all the questions applicable to your project. If it does not apply write "N/A"

A. Describe the design of the study including the investigational device or procedure in detail (e.g. double -blind, open label, etc.)

B. List all drugs (including placebo) that will be used, along with the dose regimen:

C. Indicate which procedures are part of routine care and which are experimental

D. For blood sampling state how often blood will be collected and how much will be taken each time and who will draw the blood?

E. Does the investigator or sponsor plan to communicate these results to the participants? If yes, state when.

8. POTENTIAL RISKS AND RISK MANAGEMENT PROCEDURES

A. Describe all potential risks of participating in the study, in simple terms (high, medium or low):

B. State the consequences of the risks and any possible treatment if known:

C. Describe any use of radiation including X-rays, fluoroscopy, radioisotopes or laser

D. What provisions have been made for ensuring that medical or professional intervention is available to subjects if an adverse event occurs?

9. POTENTIAL BENEFITS

A. Are there any benefits to the individual subject, scientific community and/or society by conducting this study? If yes, explain.

B. Do the potential risks, including that of participant confidentiality outweigh the benefits of this research? Explain

10. ALTERNATIVE TREATMENT(S)

A. Are there alternative drugs, devices or procedures that are available and approved for use and if so, what are they?

B. Is the proposed treatment currently available without participating in the study and if so state briefly.

C. Explain how participants will be monitored before and after the study and for how long?

11. SUBJECT PAYMENT/COSTS

A. Will subjects be paid for their participation in the study? If yes, how much and from which source will participants be paid?

B. Will there be any added expense such prolonged hospitalization, extra tests etc. as a result of a subjects participation, and if so who will be responsible for these costs?

12. INFORMED CONSENT PROCESS

A. Who will conduct the initial informed consent discussion and describe when, where and how informed consent will be obtained.

B. How do you plan to inform subjects of new information that might affect their willingness to continue in the study?

13. APPLICATION FOR WAIVER OR ALTERATION OF INFORMED CONSENT

If you do not think your research requires written informed consent or that you cannot obtain consent in person, provide the following information

A. Explain why the research involves no more than minimal risk to the subjects:

B. Explain how waiving informed consent will not adversely affect the rights and welfare of the subjects.

14. CONFIDENTIALITY OF DATA/PRIVACY OF INDIVIDUALS

A. What provisions have been made to maintain the subject's privacy (including electronic data)?

B. Where will data be stored, for how long and who will have access to the data?

15. DISCLOSURE OF FINANCIAL INTERESTS

A. Do you have any financial interests that may create a conflict of interest in this project?

◯ Yes ◯ No

B. If YES, provide details.

16. LITERATURE CITED

List between 3-8 relevant references to your study