THE UNIVERSITY OF THE WEST INDIES

ST. AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES

CAMPUS ETHICS COMMITTEE

Application for Retrospective & Survey Studies

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 invitro 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

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. 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

A. Describe the characteristics of the proposed subject population:

i. List the inclusion criteria for subjects

ii. List he exclusion criteria for subjects

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

C. How will potential subjects be selected from available population and include sample size

D. Will you identify potential subjects from hospital or clinical records, logbooks, schedules, institutional database, extramural data/tissue repository, registers or other databases? If so, state briefly source.

5. SOURCE OF RESEARCH MATERIAL

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

6. PROJECT PROTOCOL

Give detailed information about your protocol including the design of the study. List the investigational device or procedure in detail.

7. POTENTIAL BENEFITS

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

8. RISK-BENEFIT ASSESSMENT

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

9. CONFIDENTIALITY OF DATA/PRIVACY OF INDIVIDUALS

A. What provisions have been made to maintain the subject's privacy and confidentiality of data?

B. Where exactly will data be stored and for how long. Briefly state the method of storage of your data .

C. Who will have access to the data? (It is expected that the data will be stored in such a way that it cannot be easily accessed by unauthorised persons)

10. APPLICATION FOR WAIVER OF AUTHORISATION

If protected information will be used or disclosed and you have applied to waive informed consent, provide the following information to be considered for a "Waiver of Authorisation":

A. The use or disclosure of personal information involves no more than minimal risk to the privacy of individuals, based on the adequacy of the following:

1) Describe your plan for protecting data from improper use and disclosure

2) Explain when identifiers will be destroyed

3) Provide assurances that the personal health information will only be used or disclosed as described in this application

C. Explain briefly why you think the research could not practicably be conducted without access to and use of protected personal or health information

B. Explain briefly why you think the research could not practicably be conducted without waiver

11. DISCLOSURE OF FINANCIAL INTERESTS

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

◯ Yes ◯ No

If YES, provide details.

12. LITERATURE CITED

List between 3-8 relevant references to your study