FGP.P2C
2010/2011

The University of the West Indies

Policy and Procedures on Research Ethics

The School for Graduate Studies and Research*

February, 2011

* The Pro Vice Chancellor (Research) wishes to acknowledge the intellectual input of Gale Hall, Cheryl Brown, Anthony Mullings, Mike Campbell and David Rampersad in contributing to the development of a revised and expanded version of the University of the West Indies Policy and Procedures on Research Ethics; and the role of Gale Hall, with input

from Mike Campbell and David Rampersad, in preparing drafts of the document. The input of the many other UWI colleagues who made comments, suggestions and recommendations on earlier drafts is also gratefully acknowledged; their input significantly improved the quality of the document. Any errors, omissions or inaccuracies remaining are the responsibility of the Pro Vice Chancellor (Research).

Table of Contents

1. Background....4
2. Introduction....4
3. Responsibilities....4
3.1 Responsibility of the University....4
3.2 Responsibility of the Office of Research....5
3.3 Responsibility of Directors, Deans and Heads....5
3.4 Responsibility of Researchers....5
3.5 Responsibility of Supervisors of Student Researchers....5
4. Rules and Regulations....6
5. The Duty of Honesty and Integrity....6
5.1 Falsification of Data....6
5.2 Plagiarism....6
5.3 Conflict of Interest....7
5.4 Misuse of Research Funds....7
5.5 The Duty to Acknowledge Sources of Funding....7
6. Ethical Treatment of Data....7
6.1 Definition of Data....7
6.2 Gathering of Data....7
6.3 Availability of Data....8
6.4 Maintenance of Data....8
7. Collaborative Research....8
7.1 Attribution of Authorship and Copyright Ownership....8
7.1.1 Rules for the Attribution of Authorship....8
7.1.2 The Status of the Student in Attribution of Authorship....9
7.1.3 Duties of the Principal Author in Attribution of Authorship....9
7.1.4 Ownership of Copyright....9
7.2 Disputes among Co-Researchers....9
7.2.1 The Duty on the Parties to Resolve Disputes....9
7.2.2 The Duty of the University to Facilitate the Resolution of Disputes....10
8. Research Ethics Committees at the University of the West Indies....10
9. The Research Ethics Review Process....11
9.1 Exemptions from Review....11
9.2 Full Reviews....12
9.3 Expedited Review....12
9.4 Results of the Review....13
9.5 Continuing Review....13
9.6 Appellate Review....13
10. Research with Human Participants....13
11. Animal Research....14

12. Disciplinary Action and Grievance 14
Appendix 1 14
Appendix 2 17
Appendix 3 20
Appendix 4 22
Appendix 5 23
Appendix 6 26
Appendix 7 32

The University of the West Indies

Policy and Procedures on Research Ethics

1. Background

The first University of the West Indies Policy on Research Ethics was written by the then Pro Vice Chancellor Research, Professor Roger Prichard, and approved by the relevant University Committees and Boards in 1998. This document is a revision and expansion of that Policy, and will replace that Policy when the necessary University approvals are obtained.

2. Introduction

This Policy on Research Ethics should be interpreted in a manner that is consistent with the vision of the University of the West Indies (UWI) as a research community committed to the principles of honesty, trust and collegiality and to the idea that fair play must prevail at all times.

The Policy applies to all individuals who conduct research at UWI, and to individuals at affiliated institutions who submit research proposals to the UWI research ethics review system. Conducting research at UWI means research work undertaken by UWI staff and students and by all persons who use UWI facilities for the creation, dissemination and publication of research work. The term „research‟ here includes those efforts directed primarily towards the creation and dissemination of new knowledge, those efforts directed towards acquiring and representing existing knowledge (defined as „scholarship‟ in UWI Ordinance 8), as well as other forms of creative work not traditionally considered research (e.g. theatre, cinema); the term applies whether the activities are funded or unfunded.

Some of the provisions of this Policy deal with matters that are also treated in other University guidelines and regulatory documents. Where appropriate, reference should be made to these guidelines and documents.

3. Responsibilities

3.1 Responsibility of the University

The University requires honesty and integrity in research and scholarship. Through the appropriate administrative offices and in accordance with the provisions of this Policy and other applicable regulatory procedures, the University will: (a) Facilitate the training in

research ethics of all members of staff who conduct, manage or supervise human and animal research at UWI; (b) Facilitate the resolution of disputes concerning matters dealt with in this Policy (see Article 7.2); and (c) Investigate allegations of misconduct under this Policy and take action, as appropriate (see Article 12).

3.2 Responsibility of the Office of Research

The University of the West Indies Office of Research has oversight of research ethics policies and practice throughout the UWI. The Office is responsible for ensuring that the University‟s policies and procedures on research ethics are implemented and that the University community is educated on the policies and procedures. The Office is the body responsible for certifying that research projects have been subjected to ethical review and are conducted according to UWI‟s stated guidelines. The Office will provide the administrative support for the UWI Committee on Research Ethics and will support ethics activities on individual campuses when feasible.

3.3 Responsibility of Directors, Deans and Heads

Directors of Centres and Institutes, Faculty Deans and Heads of Departments are responsible for the conduct of research which falls within their jurisdiction. They are expected to be aware of the research activities conducted by the staff and students for whom they have responsibility. They are also responsible for ensuring that the University‟s policies on research ethics are publicized, promoted and adhered to.
Abstracts of all research proposals submitted to the Campus Research Ethics Committee (see Section 8) must be copied to the Head of Department and Dean, or Director in the case of Centres and Institutes. Abstracts of research proposals deemed to be exempt from ethical review (see Section 9.1) must also be copied to the Head of Department. The Deans, or Directors in the case of Centres and Institutes, shall keep a register of all research projects not submitted to the Campus Research Ethics Committee and shall provide a report of these projects (Title and Abstract) to the Campus and University Research Ethics Committees at the end of each Academic Year.

3.4 Responsibility of Researchers

The primary responsibility for the content and conduct of research rests with the individuals performing the research. Researchers bear the principal responsibility for protecting the well-being, human rights and dignity of their human participants and for the humane treatment of animal subjects. In the case of collaborative or team research, the Research Director or Principal Investigator is obliged to ensure that the members of the research team or group are aware of and are complying with the contents of this Policy, as well as with other applicable ethical norms governing the conduct of the research.

3.5 Responsibility of Supervisors of Student Researchers

All student research conducted at the University of the West Indies must be guided and supervised by a member of the University‟s faculty, even if only as a co-supervisor. Supervisors and co-supervisors are responsible for informing the student of his or her obligations in respect of the ethical conduct of research, and for taking the measures necessary to ensure that the student‟s research is conducted within the established ethical policies and guidelines.

Supervisors are also responsible for ensuring that, where required, student researchers obtain the necessary approvals prior to the start of their research project. The Chief Supervisor is responsible for co-signing the submission documents that may be necessary for ethical review of the student‟s research**.**

4. Rules and Regulations

Research projects must be conducted with due consideration for all University Policies, including, *inter alia*, this Policy, University Ordinances, the Financial Code, Financial Procedures, Financial Rules and Regulations and the University‟s Policy on Intellectual Property.

5. The Duty of Honesty and Integrity

Researchers are expected to maintain the highest standards of honesty and integrity. Any form of academic dishonesty, including but not limited to the activities identified below, is a serious offence. However, nothing in the provisions of this policy is intended to impugn the actions of a person who exercises judgment, or interprets data, or reports results in a way that may simply be the consequence of reasonable differences of opinion.

5.1 Falsification of Data

The gathering, analysis and reporting of data must be undertaken with honesty and integrity. Researchers should never publish as true, data they know to be false or the result of deliberate acts of falsification.

5.2 Plagiarism

Plagiarism is an act of academic dishonesty and is considered to be misconduct meriting severe disciplinary penalties. Researchers should not knowingly represent the published or unpublished work of another person as their own or assist anyone else in doing so. The use of work done by other persons must be appropriately and adequately acknowledged.

Upon demonstration that a researcher has misappropriated another person‟s work and represented it as his or her own, the researcher will bear the burden of rebutting the presumption of plagiarism. Procedures for dealing with the presumption of plagiarism by graduate students are provided in the University of the West Indies Policy on Graduate Student Plagiarism.

5.3 Conflict of Interest

A conflict of interest arises when the researcher has a material interest, whether personal, financial, professional, or otherwise, that may conflict with the researcher‟s duty of honesty and integrity. Where a conflict of interest arises, a researcher is required to disclose that interest to the appropriate University authorities, including the University‟s Committee on Research Ethics.

Members of any Research Ethics Committee of the University are required to disclose any actual or potential conflict of interest that may be relevant to the performance of their duties on the Committee.

5.4 Misuse of Research Funds

Where a research funding body provides guidelines on the use of research funds, Principal Investigators and other researchers must adhere to these guidelines stringently. They must also follow all University guidelines and codes relating to the management and disbursement of funds. Should misuse of research funds occur, including the failure to account for funds, offenders will be subject to the disciplinary procedures of the University under Ordinance 8.

5.5 The Duty to Acknowledge Sources of Funding

All public and private sources of funding, including grants, contracts and gifts, among others, used in the conduct of research should be acknowledged in resulting publications.

6. Ethical Treatment of Data

6.1 Definition of Data

“Data” in this document is taken to include the actual research results, the analysis and interpretations by the researchers, and the methodology used to obtain the results.

6.2 Gathering of Data

Data must be organised in a manner that allows ready verification, and must be gathered in accordance with the principles governing the use of human and animal subjects (see Articles 10 and 11).

6.3 Availability of Data

Subject to exceptions based on a duty of confidentiality and the laws respecting intellectual property and access to information, after data are published, they must be made available to any party presenting a reasonable request to examine them. Where there is a disagreement between the researcher and the person requesting the data, the matter shall be referred to the School for Graduate Studies and Research for resolution.

6.4 Maintenance of Data

All original data must be retained in paper or electronic format for at least five years from the date of publication.

7. Collaborative Research

7.1 Attribution of Authorship and Copyright Ownership

Research collaborators should establish, as early as possible, the manner in which authorship will be attributed, as well as the allocation of copyright.

7.1.1 Rules for the Attribution of Authorship

In the absence of an *a priori* agreement among researchers, the following rules will govern the attribution of authorship:

(a) Authorship is attributed to all those persons, whether staff or students, who have made significant scholarly contributions to the work and who share responsibility and accountability for the results.

(b) An administrative relationship to the investigation does not of itself qualify a person for co-authorship.

(c) The order of the names in a publication is decided according to the quality of the contribution, the extent of the responsibility and accountability for the results, and the customs of the discipline.

(d) The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status.

7.1.2 The Status of the Student in Attribution of Authorship

The guidelines and rules in Articles 7.1 and 7.1.1 apply whether the collaborators are staff or students. Further to these rules, when a multi-authored article is based primarily on a student‟s research, the student should be granted priority prominence on the list of co-authors, according to the practice in the discipline.

7.1.3 Duties of the Principal Author in Attribution of Authorship

In the absence of an *a priori* agreement among collaborating researchers, the following additional rules apply:

(a) The author who submits a manuscript for publication accepts the responsibility of including as co-authors all persons who are entitled to co-authorship, and none who are not so entitled.

(b) The submitting author should send to each co-author a draft copy of the manuscript in advance of submission, and should make every reasonable attempt to obtain consent to co-authorship, including the order of authorship.

(c) Other contributions to the manuscript should be indicated in a footnote or an „Acknowledgments‟ section, in accordance with the practice in the discipline and the publisher.

7.1.4 Ownership of Copyright

The University of the West Indies Policy on Intellectual Property, as well as relevant national legislation, governs copyright issues in relation to research undertaken by staff and students.

7.2 Disputes among Co-Researchers

The provisions of this Article govern disputes between co-researchers. They do not govern allegations of misconduct under this Policy. Allegations of misconduct are dealt with in Article 12.

7.2.1 The Duty on the Parties to Resolve Disputes

When disputes between co-researchers arise, they should be resolved amicably, in a respectful and collegial fashion, and in good faith. Where a dispute cannot be resolved by the parties themselves, they should seek the advice of the appropriate authorities in their unit, who may help them resolve the dispute in any way in which the parties may

agree, including conciliation, mediation, and binding and non-binding arbitration. To this end, the parties may agree that other persons become involved in the dispute in order to help facilitate its resolution. The parties may stipulate that their own involvement in any dispute resolution process is without prejudice to their rights in any subsequent process.

7.2.2 The Duty of the University to Facilitate the Resolution of Disputes

Although the University has no obligation to ensure that disputes are resolved, since the resolution of disputes is ultimately subject to the will of the parties to the dispute, the University has a duty to help facilitate the resolution of disputes, in accordance with the guidelines below:

- If the dispute is between individuals working under a Principal Investigator, the Principal Investigator will attempt to resolve the matter.
- If the Principal Investigator is involved in the dispute, the Head of Department, or the Dean of the Faculty if staff from more than one Department is involved, should attempt to resolve the matter.
- If the Head or Dean is involved in the dispute, or if any party involved in the dispute objects to the investigation of the Head or Dean, the Pro Vice Chancellor (Research) shall be informed and may either investigate the dispute and attempt to resolve it, or nominate a senior academic staff member, acceptable to the parties, who will attempt to resolve the matter.

8. Research Ethics Committees at the University of the West Indies

The University of the West Indies Committee on Research Ethics is the University body responsible for developing, coordinating and ensuring the implementation of the University"s policies and procedures for the ethical conduct of research. The mandate, responsibilities and composition of this Committee are provided in Appendix 1 of this document.

There will be a Campus Research Ethics Committee on each Campus that will conduct activities on that Campus on behalf of the UWI Committee on Research Ethics. The Campus Committees will review and approve, or otherwise provide feedback on, student and faculty research proposals which involve human participants, invasive or experimental work on live animals, endangered species, or research with potential to harm the environment or human groups that are not themselves the subjects of the research. The mandate, responsibilities and composition of the Campus Committee are provided in Appendix 2 of this document.

9. The Research Ethics Review Process

9.1 Exemptions from Review

Proposals for research studies on live animals that are purely observational will be exempt from review.

Proposals for research studies involving human participants will be exempt from review if they fall into any of the categories of research listed below:

- *Educational research* involving normal educational practices, e.g. classroom instruction, strategies, curricula management techniques. This exemption does not apply in cases were school records of identifiable students are involved, or where teachers and instructors or other school personnel are interviewed about identifiable students.

- *Educational Tests and Measurements*, e.g. diagnostic, aptitude and achievement tests. This exemption does not apply if the information, whether in the researchers‟ private data set or in a published form, could reasonably lead to the identification of the participants; or if the information disclosed outside of the research could place the subject at risk of criminal or civil liability or cause damage to the person‟s financial standing, employability or reputation.

- *Surveys or Interviews* in which researchers‟ private data, field notes and published materials are so encoded that there is no likelihood that the identity of the human subjects will be revealed, will normally be exempt from review, unless the nature of the questions could clearly cause distress or even harm. Surveys and interviews of minors (children) are not exempted. Researchers conducting research in the Caribbean must therefore take into consideration the legal age of consent of children in the various islands and territories of the Caribbean.

- *Public Observation*. All research involving the observation of public behaviour, including observation by participants, is exempted unless the observation is recorded in such a way that it can be linked to an identifiable human subject. However, sociological studies conducted on public personalities, such as authors, politicians and corporate leaders, or their work, are exempt, on the assumption that the resultant outputs will be guided by well established academic conventions of balance, good taste and fair play.

- *Existing Data*. Research which involves the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens is exempted if these are publically available, or if both the private data and the published material of the researcher is so recorded that there is no likelihood that the human subject may be identified, either directly or indirectly.

The categories identified above are not exempted from review if any of the research subjects are persons who are: legally incompetent (e.g. minors); significantly mentally ill or impaired; imprisoned persons, residents of a nursing facility, or persons who are in any other way involuntarily confined. The categories are also not exempt if students of the University of the West Indies are subjects of the research being conducted.

It is the responsibility of the Principal Investigator to consult with the Dean (or Director in the case of Centres and Institutes), and if so advised with the Chair of the Campus Research Ethics Committee, to determine whether any proposed study meets the criteria for exemption from review.

9.2 Full Reviews

Full Reviews will be carried out for all proposals involving invasive or experimental research on live animals, for all research which involves the capture and harvesting of endangered species, and for all research in where there is potential for significant negative environment impact.

Full Reviews will also be carried out for all research using human participants in which there is more than minimal risk to the participant(s), which involve the withholding of information on the objectives of the research or the methodology to be used from the participants, which involve participants that are members of a vulnerable or captive population, or in which there is potential for significant negative impact on human groups that are not themselves the subjects of the research. Full Reviews will also be conducted where these are required by the funding agencies to which the proposals will be submitted.

A Full Review requires the in-person convening of the relevant Campus Research Ethics Committee, which is required to render a decision on all submissions (see Article 9.4). Information requirements for research proposals in applications for ethical approval are provided in Appendix 3 of this document, and the additional information requirements when the research involves the use of live animals are provided in Appendix 4. Information requirements necessary to obtain Informed Consent of participants are provided in Appendix 5.

The results of all Full Reviews will be submitted semi-annually to the UWI Committee on Research Ethics.

9.3 Expedited Review

Expedited Reviews of proposals involving invasive or experimental research on live animals, research on endangered species, or research with significant potential environmental impact, may be conducted when the researcher is making minor modifications to a research project that has already received full approval.

Expedited Reviews of research proposals involving human participants may be conducted when the Chair of the Campus Research Ethics Committee determines that there is minimal risk or no risk to the participant(s) or other human groups, or when the researcher is making minor modifications to a research project that has already received full approval. The Chair, or a delegated Member(s) of the Committee, may conduct the Expedited Review. The results of all Expedited Reviews will be submitted semi-annually to the UWI Committee on Research Ethics.

9.4 Results of the Review

The following decisions may be taken as a result of the review process: Approved; Conditional approval subject to modifications that should lead to approval; Not approved; Not approved, but with permission to resubmit for review following significant modifications.

9.5 Continuing Review

Research projects which have been in progress for one year or more require Continuing Review as a condition of continued approval. This Review may simply take the form of Annual Reports from the Principal Investigators to the Campus Research Ethics Committee. Types of information that should be included in Annual Reports are: number of participants to date; whether data collection is ongoing; reports of adverse incidents or unanticipated events; participant complaints; instances of participants withdrawing from the study and why; and any changes to procedure and/or informed consent forms.

9.6 Appellate Review

A researcher whose research proposal has not been approved by a Campus Research Ethics Committee may appeal to the University Committee on Research Ethics, which will conduct an initial review to determine whether or not to hear the Appeal and, if warranted, conduct an Appeal hearing. Pursuant to other regulations of the University, the judgment of the University Committee on Research Ethics will be final.

10. Research with Human Participants

Research involving human participants must be carried out in accordance with the highest standards of conduct. It must be conducted in a manner which is ethical, which is respectful of the rights of the persons who are participants in the research, and which is in accordance with the rules and guidelines prescribed by research funding bodies, the relevant legislation in the countries where the research is to be conducted, and the

relevant University policies. Given this, further information on the policy and procedures for the ethical conduct of research involving human participants at UWI is provided in Appendix 6 of this document.

11. Animal Research

All animal research must be conducted in a manner which is ethical, respectful, humane and in accordance with the rules and guidelines prescribed by research funding bodies, the relevant legislation in the countries where the research is to be conducted, and the relevant University guidelines on the use of animals in research. Basic principles governing the use of animals in research at the University of the West Indies is provided in Appendix 7 of this document.

12. Disciplinary Action and Grievance

Any allegation of misconduct made against a member of the University community under this Policy shall be brought to the attention of the UWI Committee on Research Ethics. Should the Committee consider it justified, it shall refer the matter to the University Registrar for appropriate disciplinary procedures in accordance with the relevant policies and legal instruments of the University. The Research Ethics Committees are also authorised to take corrective action, including the rescinding of approval of a research project, in the event that any allegation of misconduct in research is upheld. The gathering and assessing of information in cases of alleged research misconduct can be difficult and time-consuming. The professional reputations of those involved must be fully protected throughout the process, particularly since, following investigation, the allegations may not hold.

Appendix 1

The University of the West Indies (UWI) Committee on Research Ethics

The University of the West Indies (UWI) Committee on Research Ethics is the University body responsible for developing, coordinating and ensuring the implementation of the University‟s policies and procedures for the ethical conduct of research. The Committee‟s main goals are to:

- Protect the dignity, human rights, health, safety and privacy of human participants in research.
- Ensure the care and humane treatment of animals used in the conduct of research.
- Ensure that research on endangered species is responsible and sensitive to the conservation status of the species.

- Ensure that research is sensitive to negative environmental impacts and to negative impacts on human groups that are not themselves the subjects of the research.
- Promote a culture of ethics in research at the UWI.
- Promote the reputation of the University as a centre of ethical and high quality research.
- Ensure the health and safety of researchers.

The Committee will be chaired by the Pro Vice Chancellor, Research (or his/her nominee), and will consist of the following persons (or their nominees)*:

- The Chairs of the Campus Committees on Research Ethics at each Campus (see Appendix 2).
- A representative of each of the Campus Principals.
- The University of the West Indies Legal Counsel.
- The Pro Vice Chancellor (Graduate Studies).
- Two community representatives who are not associated with the UWI.[1]

The Committee may draw upon additional members, as may be necessary for it to effectively fulfill its responsibilities.

The main functions of the Committee will be to:

- Develop and review policies, guidelines and procedures relating to research ethics at UWI.
- Respond to issues raised by the Campus Committees on Research Ethics and to audit and provide general guidance to the Campus Committees.
- Promote training in ethics in research at UWI.
- Provide assurance of the ethical conduct of research at UWI, particularly that involving human and animal subjects.
- Serve as the Final Appeal Committee on research ethics disputes for all Campuses.
- Based on information provided by the Campus Research Ethics Committees, maintain a Register of proposed and approved research proposals submitted to those Committees.
- Report to the University Council on the ethical conduct of research at the UWI.

The Committee will meet at least twice per year. The Chairman may act on behalf of the Committee between meetings, but at the next meeting will report to the Committee on any actions taken on its behalf.

[1] Should the proposed University of the West Indies Centre for Ethics be established, the Director of that Centre will be a Member of the UWI Committee on Research Ethics.

Appendix 2

Campus Research Ethics Committees

There will be a Research Ethics Committee on each Campus that will conduct activities on that Campus on behalf of the UWI Committee on Research Ethics. The Campus Committees will be formed through appropriate modifications of any existing Research Ethics Committees currently operative on the Campuses. The Campus Committees will review and approve, or otherwise provide feedback on, all student and faculty research proposals which involve human participants (but see Exemptions in Article 9.1), or have the potential to negatively impact human groups that are not themselves the subjects of the research; as well as all proposals involving invasive or experimental procedures on live animals, requiring the collection and harvesting of endangered species, or having the potential to result in significant negative environmental impact. No research involving any of the above will proceed without the explicit and written approval of the relevant Campus Committee.

The principal responsibilities of the Campus Research Ethics Committees are to:

- Review prospectively all research protocols involving human subjects to ensure that they meet the required ethical and scientific standards, as well as those protocols with the potential to impact negatively on human groups that are not themselves the subjects of the research.
- Review prospectively all protocols involving experimental or invasive procedures on animals to ensure their humane treatment in accordance with UWI guidelines, national legislation and international best practice.
- Review prospectively all protocols involving the use of endangered species, as well as those with potential for significant negative environmental impact.
- Monitor practices for recruiting individuals in research involving human participants to manage multiple enrolments and misuse of relational power in the recruitment process.
- Monitor those approved research projects which have the potential for significant risk of harm to research subjects, with the Committee being empowered to disallow unacceptable research to continue.
- Record all review decisions and monitoring activities, and submit them in semiannual reports to the UWI Committee on Research Ethics, necessary for the University Committee to maintain its Register on research involving humans and animal subjects.
- Investigate and make recommendations on ethical problems related to the conduct of researchers.
- Assist the UWI Committee on Research Ethics in the development of new institutional policies and procedures related to research ethics.
- Assist the UWI Committee on Research Ethics in its efforts to provide training in research ethics at UWI.

- Encourage researchers and participants in research to bring to the Committee matters deemed to be of ethical importance.

The information required by Campus Research Ethics Committees in research proposals seeking ethical approval is provided in Appendix 3 of this document. The additional information required to be submitted to Campus Committees in research proposals involving invasive or experimental work on live animals, or involving endangered species, is provided in Appendix 4. The information required to obtain Informed Consent in research applications involving human participants is provided in Appendix 5.

The Campus Research Ethics Committee will consist of a core membership (Core Members) of at least six persons who will be invited to participate in all meetings of the Committee. The Core Membership must: Include at least one representative from the medical sciences, one representative from the pure and applied sciences or engineering, and one representative from education, humanities and the social sciences at UWI; Two non-UWI community members; Be generally interested in and knowledgeable about ethical issues in research; Be willing to undertake formal training in research ethics when such opportunities arise. The Campus Coordinator for Graduate Studies and Research will be a Core Member of the Campus Research Ethics Committee. Administrative Support for the Committee must be adequate enough to ensure that the Committee can function in an efficient and effective manner. The administrative arrangements in support of the Committee will be those preferred on individual Campuses.

Apart from its Core Membership, the Committee will also consist of at least four more Members, each with specific expertise in the ethical issues relating to their particular discipline (Discipline Members). Discipline Members will be obligated to participate only in those meetings reviewing protocols in their disciplines, but will have the option to participate in any meeting that they choose to. They will in effect be Specialized Panels dealing with projects coming from particular disciplines or groups of disciplines. The Chair of the Campus Research Ethics Committee may ask a Specialized Panel to serve as a sub-committee to review and make recommendations to the Campus Committee on a particular set of protocols. In such a case, the sub-committee must include the appropriate Discipline Member(s) and at least two Core Members of the Campus Committee.

The Chair of the Committee may also appoint *ad hoc* Members, or obtain external advice, when reviewing a proposal which requires highly specific technical expertise because of its subject matter or proposed methodology.

Six persons shall be considered the minimum quorum for a Meeting to convene, but a larger number is clearly desirable to ensure adequate representation and participation.

Members of the Campus Committee will not participate in the review of projects in which they or their students are investigators.

The Pro Vice Chancellor (Research), in consultation with the appropriate Campus Principals, may appoint Campus Committee members for a period of three years in the first instance, but Members may be reappointed for a subsequent term.

Campus Committees will meet at least quarterly to review research submissions, but more frequently if demand requires.

The University Research Ethics Committee may pursue registration or accreditation of individual Campus Research Ethics Committees with external agencies, as appropriate and valuable.

The University recognises the level of commitment required for Research Ethics Committee service and will take this into account in decisions relating to assessment, promotion and distribution of workload.

Appendix 3

Campus Research Ethics Committee

Information Requirements for Research Proposals in Applications for Ethical Approval

1. A Cover Page that includes:
    - The Title of the Research Project.
    - The Names of the Investigators and Collaborators, with affiliations.
    - An Abstract that summarises the Aims, Methodology, Location and Time Frame for the Study.
    - The Signature of the Principal Investigator
      If the Investigator is a student, the Cover Page must also include the name of the student‟s Supervisor and the Supervisor‟s signature indicating support of the Project.
2. Background and Rationale for Study
3. Aims, Objectives and Hypotheses (if applicable)
4. Methodological and Financial Details of the Study
    - Overall Study Design
    - Location and Time Frame of Study
    - Participants or subjects (Study Population), inclusion and exclusion criteria and sample size
    - Data Collection Instruments (e.g. measurements, questionnaires)
    - Methods of Data Analysis
    - Materials and Procedures to be administered to participants or subjects (e.g. drugs, diet)
    - Treatments or beneficial procedures that may be withheld from participants
    - Samples to be taken from participants or subjects, including methods of processing
    - Discomfort, inconvenience, side effects and financial costs to participants
    - Benefits to participants, including payments or payments in kind
    - Impacts of the study on human groups that are not participants in the study (where applicable)
    - Impacts of the study on the environment (where applicable)
    - Funding Sources for the Project
5. Confidentiality
    - Methods for storing and securing study data
    - Methods for protecting participants‟ confidentiality
6. Expected Outcomes of the Project
    - How the results will be disseminated (reporting, publication)
    - How the results will be acted upon for both the participants and the community
7. Qualifications of the Principal Investigator and Collaborators

All applications must be presented under the above headings. If a particular heading is not applicable, indicate with N/A. Submissions not in this format may be returned without review.

Appendix 4

Additional Information Requirements by Campus Research Ethics Committees for Research Proposals involving Invasive or Experimental work on Live Animals as well as work on Endangered Species

1. Provide the species, variety, conservation status, sex, age and source of the animals to be used (where available),and state the total number of each species needed for the project.

2. Justification of animal use: Explain why the proposed use of the animal (or endangered species) is required, what alternative approaches are available and how the numbers used will be minimized. Provide a justification of the numbers to be used, as well as their prior history (if applicable and available).

3. If applicable, state where the animals will be housed, who will care for them, how they will be maintained and who will carry out any anaesthesia, surgery or euthanasia required.

4. State the Use of the Animals in the Research:

    - Animals to be treated under anaesthesia, (and/or) administered or deprived of materials, (and/or) subjected to unusual conditions. All animals expected to recover at termination of research.
    - Animals to be treated under anaesthesia and killed without regaining consciousness.
    - Animals to be killed for preparation of tissues.
    - Animals to be used for antisera production by standard techniques.
    - Any other uses.

5. Describe the anaesthesia or euthanasia procedures (if applicable). Give specific drugs, doses and routes of administration.

6. Describe the surgical procedures (if applicable). Give details for each type of operation.

7. Describe the provisions for post-research recovery and care (if applicable).

8. Indicate the fate of the animals following their recovery and the conclusion of the study.

9. In the case of endangered species, indicate the fate of the individuals on completion of the project.

10. In the case of endangered species, indicate the impact of the project on the conservation status of the species.

Appendix 5

Campus Research Ethics Committee

Information Requirements to obtain Informed Consent and for Completion of the Informed Consent Form in Applications to the Campus Committee for Ethical Approval* □

Identification of Project:

- Provide the Title of the project
- Provide the names of the Investigators and other key personnel participating in the project, indicating qualifications
- Explain that the project involves research

Purpose of the Research and Invitation to Participate:

- Explain the purpose of the research and how long it will take to complete the project
- Invite the person to participate and explain why they were selected
- Indicate the need for parental or guardian‟s consent, if subject is under age of legal consent

Description of Procedures:

- Explain what you expect the participant to do in the study
- Describe the procedures to be followed and indicate which procedures are investigational
- Indicate the expected duration and frequency of the person‟s participation and where the activities will take place

Risks and Discomforts:

- Inform the participants of any risks or discomforts that may result from their participation in the study and provide an estimate of their likelihood
- Inform the participants of help or treatments that are available if any adverse reactions occur and how they may be obtained
- Inform the participants of any potentially beneficial treatments or procedures that may be withheld for the purpose of the study

Benefits:

 Components of this information may not be applicable for all types of proposals.

- Describe the benefits to the participant and the wider society, including other patients in the future, that may reasonably be expected as a result of the study
- State clearly if there is no direct benefit to the participant, but only societal benefit

Alternatives:

- For a study which involves more than minimal risk, indicate appropriate alternative procedures or courses of treatment that might be advantageous to the participant
- Emphasise the participant‟s right to pursue the alternatives

Confidentiality:

- Explain to the participant how confidentiality will be maintained, who will have access to the data, how the data will be reported in order to maintain the individual‟s confidentiality, and how and where the data will be published or reported
- Inform the participant if confidentiality will not be maintained

Cost and Payments:

- Explain the type of costs that might be expected and any compensation that can be provided
- Ensure that payment is not consequential and therefore seen to be an inducement

Freedom to Withdraw:

- Explain that participation is voluntary and that participants are free to withdraw at any time if any problems occur or if they simply change their minds. Participants will have the option to exclude from the study data obtained through their participation, should they decide to withdraw
- Explain that refusal to participate or withdrawal thereafter will not adversely affect the participant‟s relationship with the Investigator(s) or their right to any other treatment or services available to them at the University of the West Indies or its affiliated institutions

Opportunity to ask Questions:

- Explain that the participant has the right to ask questions and to have them answered before the start of the study
- List the names and telephone numbers of persons who can be contacted for answers to questions about the study (this list should include at least one member of the Campus Research Ethics Committee).

CONSENT AND SIGNATURE

I confirm that the purpose of the research, the study procedures, and any possible risks or discomforts, as well as the possible benefits that I may receive by taking part in the study, have been explained to me. Alternatives to my taking part have also been discussed and all my questions have been answered. I further confirm that I have been provided with the telephone number(s) of the Principal Investigator for contact in the case of an emergency. I have read this Consent Form and my signature below confirms that I am willing to take part in this study.

Participant‟s Name (print) _____

Participant‟s Signature _____

Date _____

Name and Signature of Parent, Guardian or Legally Authorised Representative (if participant is below the age of legal consent; note that certain types of research may require that the requirement for parental consent be waived).

_____

Date _____

INVESTIGATOR'S STATEMENT AND SIGNATURE

I have explained the purpose of the research, the study procedures, including those that are investigational, the possible risks and discomforts, and the potential benefits, and have answered all questions regarding the study to the best of my ability. In my opinion, the participant understands these issues and has voluntarily agreed to participate in the study.

Name and Signature of Investigator obtaining Informed Consent:

Date _____

A copy of the signed Informed Consent Form must be left with each participant.

Appendix 6

Policy and Procedures for the Ethical Conduct of Research involving Human Participants at the UWI

1. Preamble

The University of the West Indies is strongly committed to the protection of human participants in research and is guided by the principles of (a) respect for persons, (b) beneficence or concern for the well being of participants and (c) justice, as outlined in The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (The Belmont Report, 1979). The University also subscribes to the principles and philosophy articulated by the World Medical Association (commencing with Alma Ata and Helsinki; most recent revision in 2008) and the Council for International Organisations of Medical Sciences (2009). This policy hereby sets out the Policies, Procedures and administrative structures for the ethical review of human subject research, in all faculties of the University of the West Indies.

2. Definitions

2.1 Research

Research means a systematic investigation designed to develop or contribute to generalized knowledge. Pilot Testing is usually considered part of the research[2], but need not require ethical approval unless the testing may itself engender risk of harm.

Class room instruction, surveys for evaluating the performance of faculty or students, or studies for institutional use only, students‟ coursework and undergraduate theses (unless the intention is to make them available to the public or to other researchers) are not considered part of research for the purposes of this policy. However, UWI faculty members, especially Supervisors, must ensure that all student researchers ensure the well-being of their participants even when the work does not qualify as research.

2.2 Human participants

Human subject refers to a living person about whom a researcher obtains (a) data through interventions or interactions with the person or (b) identifiable private information

[2] US Office of Human Subject Research. Code of Federal Regulations Title 45 Public Welfare Part 46 Protection of Human Subjects P.6

(observations or private record). A person may be a human participant when a researcher obtains data about him/her from a third party as well as from the person directly[3].

2.3 Interventions

Interventions include both medical and physical procedures and manipulation of the participant or the participant‟s environment that are performed for research purposes.[3]

2.4 Interaction

Interaction includes communication or interpersonal contact between investigator and participant.

2.5 Identifiable

Identifiable implies that the identity of the participant is or may be readily ascertained by the investigator or associated with the information obtained as part of the research.[4]

2.6 Private information

Private information includes information about behaviour that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. medical record).[5]

2.7 Conducted or sponsored at UWI

Conducted or sponsored at UWI means:

- Using facilities at UWI ○ Paid for by UWI or Campus funds
- Conducted as a prerequisite for obtaining a degree at UWI ○ Conducted by UWI faculty members or employees in the course of employment at UWI
- Using UWI staff or students as participants

2.8 Minimal Risk

Risk refers to the probability of harm which may reasonably be anticipated in connection with the proposed research. Research will be deemed to involve no more than minimal risk, if it does not increase the participant‟s risk of harm either in probability of magnitude, beyond those risks, which are inherent in ordinary daily living.[6]

[3] US Office of Human Subject Research. Code of Federal Regulations Title 45 Public Welfare Part 46 Protection of

Human Subjects
[3] Ibid [4] Ibid [5] Ibid
[6] University of Arkansas, Fayetteville - Policy and Procedures, Governing Research with Human Subjects. P2.

2.9 Protocol

Protocol refers to the researcher‟s written research plan, which is submitted to the Campus Research Ethics Committee.

3. Advance Submission of Protocol

Researchers are required to submit a protocol to the Campus Research Ethics Committee if the proposed research involves human participants and is not exempted. The protocol must be reviewed and approved by the Committee before the research begins. The University of the West Indies will not grant retroactive approval of research protocols.

4. Requirement for Informed Consent

Informed consent is a decision to participate in research taken by a competent individual who has received all the information necessary to arrive at an informed decision. The individual is required to have understood the information, considered the information and to have arrived at the decision without coercion, undue influence inducement or intimidation[4].

In almost all cases, the researcher must obtain the informed consent of each participant **prior** to the start of the research activities.

In cases where the participant lacks capacity to provide informed consent, the researcher must obtain the consent of the participant‟s legally authorized representative, e.g., parent or guardian.

The researcher must ensure that the participant, or his or her legal representative, is provided with sufficient opportunity and time to understand and carefully consider the request to participate in the research and thereby minimize the possibility that the consent is obtained through undue pressure, haste or influence.

The researcher must also ensure that the information provided to the participant or his/her representative is in clearly understandable language. Informing the individual must not be

[4] The Council for International Organizations of Medical Sciences in collaboration with the WHO International Ethical Guidelines for Biomedical research Involving Human Subjects p.20

simply a ritual recitation of the content of a written document[5]. That is, in words and terms appropriate to the educational level of the participants. Every effort must be made to avoid the use of jargon and technical terms.

Under no condition must the researcher appear to encourage the participant to waive any of his/her legal rights including releasing the researcher the sponsor or the University from any liability due to negligence.

5. Specific Considerations for Research with Children

In addition to obtaining the consent of parents or guardians, researchers must still attempt to obtain the real consent of the child as long as the child is old enough to understand the principle of consent. Older children should be encouraged to sign the consent form with their parent or guardian. The researcher should also clearly explain to younger children that what they are doing is voluntary and that they could refuse to take part or withdrew if they wish. Even in cases where parental consent is obtained, researchers should not coerce children to continue participating in the absence of the child's assent. Assent is not required for essential medical treatment if parental consent for treatment is in place.

6. Specific Considerations For Research With Vulnerable Populations

Campus Research Ethics Committees at UWI must make every reasonable effort to consider and protect the unique needs and rights of vulnerable groups, including, among others, prisoners, persons with disability, persons with reduced capacity for consent, and pregnant women. When considering projects involving vulnerable groups, Committees should make every effort to consult with advocates or members of the relevant group to inform the deliberations.

7. Research Involving Withholding Full Information on Research Objectives or Methodologies

Certain types of research in certain disciplines, e.g., psychology, may require the withholding of full information about the objectives of the research from the particpants. In such cases, the researcher may request the use of a modified Informed Consent form. In other types of research, it may be necessary to conduct surveillance (e.g. criminological research).

The Campus Research Ethics Committee must pay particular attention to these cases. Where it is established that this type of research will contribute to knowledge and understanding, the researcher is expected to justify that alternative procedures are not available or feasible and that the withholding of information is integral to the viability of the research. The researcher is still expected to obtain the participant‟s consent and to

[5] Ibid p.20

make the participant aware that information was withheld, as well as to inform the participant of what results were obtained, as soon as possible.

8. The Use of the Internet

The UWI Policy on Research Ethics and the conduct of research with human participants also apply to internet-based research. Use of the internet may present unique risks to confidentiality; however, the technologies for on-line data collection are developing. When researchers collect or manage data via internet, they are responsible for taking the best available security precautions and for ensuring that the Informed Consent procedures accurately portray the risks associated with their research.

9. Collaborative Research with other Institutions

In cases where the research is to be conducted with researchers from other universities or organizations which do not have a Research Ethics Committee, a full application must be submitted to the Campus Research Ethics Committee on the relevant Campus of UWI.

Where a UWI researcher conducts research with a researcher from another institution where there is a fully functional Research Ethics Committee, the approval will be sought from the Research Ethics Committee of the Principal Investigator. It will be the responsibility of the UWI researcher to submit a copy of the approval to the relevant UWI Campus Ethics Committee. The UWI Campus Research Ethics Committee may ratify the approval or request the UWI researcher to submit a full application

10. New Staff

A new faculty member who brings a grant from another institution must provide the Campus Research Ethics Committee with a copy of the original ethics approval for its review. The researcher must obtain written approval from the UWI Committee before proceeding with the research at UWI.

11. Submission of Research Protocols

Research protocols may be submitted at any time during the year but at least six weeks prior to the start of the project. Since many donors require a certification of ethics approval, researchers should submit the request for approval from the relevant Campus Research Ethics Committee before the grant application is submitted.

Researchers are expected to submit 5 copies of the research protocols, of all questionnaires which are to be administered, and of the Informed Consent Form.

The Faculties of Medicine have Faculty-specific Guidelines which should be used by them in conjunction with the above Policy. The Guidelines are subject to review by the University Committee on Research Ethics.

Appendix 7

Basic Principles Governing the Use of Live Animals and Endangered Species in Research at the University of the West Indies

- The advancement of biological knowledge and the development of improved means for the protection of the health and well-being both of man and of animals may require recourse to experimentation on intact live animals of a wide variety of species.

- Methods such as mathematical models, computer simulation and *in vitro* biological systems should be used wherever appropriate.

- Animal experiments should be undertaken only after due consideration of their relevance for human or animal health and the advancement of biological knowledge.

- The animals selected for an experiment should be of an appropriate species and quality, and should be the minimum number required to obtain scientifically valid results.

- Investigators and other personnel should never fail to treat animals as sentient, and should regard their proper care and use and the avoidance or minimization of discomfort, distress, or pain as ethical imperatives.

- Investigators should assume that procedures which would cause pain in human beings cause pain in other vertebrate species.

- Procedures with animals that may cause more than momentary or minimal pain or distress should be performed with appropriate sedation, analgesia, or anesthesia in accordance with accepted veterinary practice. Surgical or other painful procedures should not be performed on unanesthetized animals paralysed by chemical agents.

- At the end of, or when appropriate during, an experiment, animals that would otherwise suffer severe or chronic pain, distress, discomfort, or disablement that cannot be relieved should be painlessly killed.

- The best possible living conditions should be maintained for animals kept for research purposes. Ideally, the care of such animals should be under the overall supervision of persons with substantial experience in laboratory animal science.

- It is the responsibility of the Director of a Centre or Institute, or Head of Department, using animals to ensure that investigators and personnel have appropriate qualifications or experience for conducting procedures on animals. Adequate opportunities shall be provided for in-service training, including the proper and humane concern for the animals under their care.

- Research which involves the collection and harvesting of endangered species should be allowed only after careful consideration of its relevance to the advancement of knowledge and its impact on the conservation status of the species; and the numbers harvested should be kept to the absolute minimum necessary to obtain scientifically valid results.

- Where waivers are required from any of these Guiding Principles, a request for the waiver must be made to the appropriate Campus Research Ethics Committee, who may refer it to the University Committee on Research Ethics.

The above Principles governing the use of animals in research are based primarily on the Council for International Organisations of Medical Sciences (CIOMS): International Guiding Principles for Biomedical Research Involving Animals.