

**POLICY AND CODE ON RESEARCH ETHICS FOR THE UNIVERSITY OF**  
**THE WEST INDIES**

**POLICY STATEMENT**

The University of the West Indies recognizes the need to have guidelines to ensure the ethical conduct of research by and or in collaboration with its staff, agencies or through any other arrangement which makes the University or its agents a party to the research. In recognition of this position, the University hereby establishes a University of the West Indies **Code of Ethics for Research** as set out hereunder and requires that all research activity shall in all material ways be in compliance with this code. "This CODE on Research Ethics applies to all individuals who conduct research at The University of the West Indies (UWI) or at one of its **affiliated** institutions. The term "research" includes all off funded and unfunded scholarly and creative work by UWI staff and students and by people who use UWI facilities for the creation, dissemination and publication of scholarly work." (1998)

The University further states that it is the responsibility of the Principal Investigator who shall be an employee or other such person as agreed to by the University to ensure the compliance with this Code.

The following are covered under the **Code** with regard to human subjects within all Faculties, but does not provide an exhaustive list.

- Survey research
- Needs assessments
- Interviews with students, teachers
- .Participant/observation studies
- Research on "captive" or dependent populations, for example, prisoners, school children
- Research on other cultures, countries and/or ethnic groups
- .Archival research, in certain instances. .
- Any research of a medical nature
- Any research by students, both undergraduate and graduate

**The Institutions Affiliated to the University of the West Indies in the three Campus Countries as well as the non-Campus territories are covered under this Code.**

Bethlehem Community College  
Brown's Town Community College  
Excelsior Community College (EXED)  
Institute of Management & Production (IMP)  
Institute of Management Sciences (IMS)  
Knox Community College  
Management Institute for National Development (MIND)  
Moneague Community College  
Montego Bay Community College  
Portmore Community College

*[We need not insert here all the institutions affiliated in Jamaica, Barbados and St. Augustine as they will change from time to time but if required as a guide, the list can be put as an appendix at the back of the document]*

The University states that monitoring for compliance with this Code shall be the responsibility of a University Research Ethics Committee supported by a Campus Research Ethics Committee. All other monitoring committees (for example any Departmental committee) shall report through the Campus Committee to the University Committee.

**University Research Ethics Committee  
Mechanics of the Code/ Implementation**

*[Please note that it is our strong belief that if this process/procedure becomes too involved and cumbersome, it will be a dis-incentive to the academics.*

*We are working on having several categories of research, starting with those which do no harm (physical or emotional) and thus, do not need review or if they do, this could be done as an executive review according to criteria laid down in the several Faculties. Once the criteria are met then the review process would have been deemed to be completed and the protocol exempt from review by the Committee which essentially requires/would require members to comment on and discuss in committee. }*

*"Research on the effectiveness of instructional techniques, curricula, or management methods;*

*Research involving interview and survey procedures, observation of behaviour, or educational tests, where participants are not personally identifiable. .." ]*

*This Policy is to be interpreted in accordance with other relevant policies of the University of the West Indies:*

*Ordinance 8 and The Students' Charter.*

*The Policy on Intellectual Property*

*UWI'S Guidelines on the use of Animals for Research an Teaching.*

Sanctions that may be applied by the University do not protect against any other legal action on behalf of an individual, group, organization or the state.

**A. PREAMBLE**

A Code is usually developed in response to a policy.

In writing a Code of Ethics relating to research one should ask what are the unethical action one's organization wishes to prevent and how this can be achieved.

The code should not only state the principles but state how they should be followed and should be general enough to be used in a variety of situations but give enough information to be used in specific situations as well. The Code can not be too brief as it will then not give sufficient guidance and there has to be broad agreement and consensus with respect to fundamental principles.

A code is a "living document" and often has to change to reflect changes in the organization's ethos.

**Values & Conflicts**

The development of this Code recognizes that:

- ✓ Each individual has his/her own set of values as to what is ethical and proper research behaviour and recognizes that values are influenced by such considerations as:

Harms

Risks

Benefits

Autonomy

Financial & Special interests  
Cultural norms  
Religious beliefs  
Moral values

- ✓ Values are by nature subjective and what is deemed "right" and permissible by one person might be anathema to another.
- ✓ Universities are, by their very nature, a melting pot of people from different cultures and value-systems.
- ✓ Bodies that fund research expect that the University's research will be conducted within a framework of explicitly stated policies.

## THE CODE

### PREAMBLE / INTRODUCTION

"**Ethics** consists of those morally permissible standards of conduct each member of a group wants every other member to follow even if their following them would mean he or she has to follow them too".

"**Codes of ethics** are reflections of the morally permissible standards of conduct which members of a group make binding upon themselves."

- ✓ It is important for any University to have an explicitly stated ethical framework within which all professional activity including research should be conducted.
- ✓ Research as a scientific enterprise, like other human activities, is built on a foundation of trust. There is a trust that the results reported by others are valid.
- ✓ The sociological value of a code of ethics is expressed by both *Heinz Luegenbiehl* and Stephen Unger.

**Luegenbiehl**, although he had his doubts about the overall value of such a code stated that "The adoption of a code is significant for the professionalization of an occupational group (or activity), because it is one of the external hallmarks testifying to the claim that the group recognizes an obligation to society that transcends mere economic self-interest".

**Unger**, on the other hand set out six reasons for a Code: "First, it can serve as a collective recognition by members of a profession of its responsibilities. Second, it can help create an environment in which ethical behavior is the norm. Third, it can serve as a guide or reminder in specific situations.. Fourth, the process of developing and modifying a code of ethics can be valuable for a profession. Fifth, a code can serve as an educational tool, providing a focal point for discussion in classes and professional meetings. Finally, a code can indicate to others that the profession is seriously concerned with responsible, professional conduct ."

These "Ethics" are the rules of conduct and the standards governing how research is carried out within the institution.

Knowledge transfer and research are basically the functions of a university and for these to take place, scholars have to be assured of certain basic rights and freedoms. But along with these rights and freedoms come the concomitant responsibilities.

This is, perhaps, the fundamental reason for a policy on research and a Code of ethics for research as it is incumbent on researchers, given the freedoms with which they are

furnished to respect established professional ethics (established ethical principles) which pertain to the health, safety, privacy and other personal rights of human beings "or to the infliction of injury or pain on animals." (Or harm to and destruction of the environment).

In this regard there have been, since time immemorial codes to guide the behaviour of all humans. Established ethical principles apply to all fields of research. The most basic fields of research are:

Educational  
Social  
Behavioural  
Biomedical

### **Some Historical Perspectives**

1. *Hippocrates*: There are two main aspects to the Hippocratic Oath. "do no harm" and the second is "confidentiality"
2. *Nuremberg Code* (1947). This consisted of ten principles. Two of the major ones are:
  - The rights of subjects
  - To yield fruitful results plus the protection of the welfare of the subject
3. *The Tuskegee Study* (1932-72)

(This was when treatment was denied to Blacks with syphilis). Among the lessons learnt were the following:

Duty to vulnerable subjects  
Need for periodic review  
Informed consent  
Protection of a subject's rights

4. *The Belmont Report* (1979)

**(This is the major ethical statement guiding human research in the United States of America ).**

This report has three (3) major principles:

*Respect for persons*: Vulnerable persons with diminished autonomy need extremely accurate information

*Beneficence*

Do no harm  
Maximise benefits  
Minimise possible harms

*Justice* ie. the balancing of the benefits and burdens of research

5. *The Declaration of Helsinki* (1964)

(Adopted by the World Medical Association.) This calls for review by an independent committee among other things

6. *CIOMS* (established in 1949 by WHO and UNESCO) -Council for International Organization of Medical Sciences.

This represents the international ethical guidelines for biomedical research involving human subjects.

## **B. Definition of Terms**

*Research*

*Researcher*

*Research Participation Agreement*

*Data*

*Student*

*Supervisor*

*Author*

*Ownership Credit*

*Human Subject*

*Conflict of Interest*

*Conflict of Commitment*

*Negligence*

*Misconduct*

*Transparency*

*Deception*

*Plagiarism*

*Misuse of research funds*

### **Research**

A systematic investigation designed to develop or contribute to general knowledge. It usually involves the development of an idea, the collection and study of relevant data and the publication of such findings as a result of this activity.

### **Researcher**

Any person who is involved in research as defined above

### **Research participation agreement**

The exchange of ideas and research techniques between the private and non-profit sectors has proven mutually beneficial and has resulted in many important scientific developments. This collaboration has increased in recent years and many of the academic research facilities at the UWI are used to assist industries in ways that are consistent with the primary teaching, research and public service missions of the University .

A Research Participation Agreement (RPA) is a form of sponsored project in which the services of UWI personnel, academic facilities and/or laboratory equipment are employed on behalf of parties not otherwise affiliated with the University as faculty, staff or students. Faculty relationship to the project may range from the degree of oversight required by the Policy Statement through the full intellectual involvement characteristic of principal investigatorship except that the project requirements may be established in detail by the sponsor. Work on the project will, under normal conditions, be conducted by UWI personnel.

## **Date**

"Data" include the methodology used to obtain results, the actual research results and the analysis and interpretations by the researchers.

The gathering of data and research materials 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.

Researchers have to be extremely clear, both to themselves and to others, about the methods being used to gather and analyze data. Other scientists will be judging not only the validity of the data, but also the validity and accuracy of the methods used to derive those data.

## **Gathering of Data**

Data must be organized in a manner that allows ready verification. Data must be gathered in accordance with principles governing the use of human and animal subjects.

## **Tampering With Data**

Modifying the data to achieve the ends you require either through falsification or deliberate misinterpretation.

## **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, with justification, to examine them. In cases where there is a disagreement between the researcher and the person requesting the data, the matter shall be referred to the Research Ethics Committee.

## **Maintenance and Retention of Data**

All original data must be retained for a reasonable length of time. This should be for at least five years from the date of publication. A student cannot be a PI who has the responsibility to legally maintain the data.

## **Student**

Any person who is officially registered in one of the academic programmes offered by the University. (See the meaning assigned to it in the Statutes of the University).

## **Supervisor**

The person in whose charge a student is put when pursuing research activities.

## **Author**

A person named as the creator of any scholarly work such as lecture notes; books; articles, monographs *inter alia*.

The principal author shall be the person so named in the work and if not named shall be the corresponding author.

**Attribution of Authorship:** In the absence of an agreement between the researchers (including students) the following rules governing the authorship apply:

Authorship is attributed to all those persons (including students) who have made significant scholarly contributions to the work and who share responsibility and accountability for the results;

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

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 custom of the discipline and must fully respect the contributions of students as previously stated.

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

Where multi-authored work is based primarily on the student's dissertation/thesis, the student should have a position of priority on the list of co-authors, according to the practice in the discipline

#### *Duties of the Principal Author*

Research collaborators should establish as early as possible, how the attribution of authorship and how the allocation of copyright are to be divided between them.

I In the absence of an agreement between the researchers, where there are co-authors, the following further rules apply:

the author who submits a manuscript for publication accepts the responsibility of having included as co-authors all persons who are entitled to co-authorship, and none who are inappropriate

The submitting author should send each co-author (including students) a draft copy of the manuscript and should make a reasonable attempt to obtain consent to co-authorship, including the order of names

Other contributions should be indicated in a footnote or an "Acknowledgements" section, in accordance with the standards of the discipline or the publisher.

The allocation of copyright is governed by University policy and law.

#### **Ownership**

In the absence of an agreement between the researchers -where there is collaboration – ownership is construed strictly within the University's Policy on Intellectual Policy. (See s 2 "Ownership of Inventions", page 13)

#### **Credit**

Because of the nature of the recognition that is awarded for research work, it is imperative that proper credit be given to the creators of research. Acknowledgements are to be made in the order which best reflects the importance of the individual's input. One should note that consistent failure to give due credit to the work of others can result not only in litigation but in a researcher being excluded from the company of his /her peers. This is particularly so since this is such an important part of the reward system of academia. -

It is important to note that credit re research or publications also means responsibility if something should be found to be wrong with the research, or if there is error or deceit involved.

This becomes a major issue when one has to list names in a work of joint ownership. It is even more sensitive when the authors/researchers are at different stages of their careers - for example, Professor/ student.

### **Human subject**

A living subject, post mortem remains and stored specimens about whom a researcher obtains

- a) data through interaction
- b) identifiable private information ego Questionnaires; pilot studies; oral history interviews.
- c) stored data from which a researcher obtains identifiable private information.

NB. There are no timeframe influences in this.

The following are covered under this **Code** with regard to human subjects:

Survey research

Needs assessments

Interviews with students, teachers

Participant/observation studies

Research on "captive" or dependent populations, for example, prisoners, school children

Research on other cultures, countries and/or ethnic groups

Archival research, in certain instances.

All biomedical research. (See section on Biomedical Research)

### **Conflicts of Interest /Commitment**

*A conflict of interest* may arise when the researcher has a material interest -financial or otherwise -that may conflict with the researcher's duty of honesty and integrity. Where a conflict of interest of a financial nature arises, a researcher is under a duty to disclose that interest to his/her superior and to all other persons to whom it should be disclosed, where the relevant circumstances are not a matter of public knowledge.

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University. Such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation and not on the character or actions of the individual.

The following points of policy relate to conflicts of interest:

Academic Staff must foster the open and timely exchange of results of scholarly activities, informing faculty, students and colleagues about outside obligations that might influence the free exchange of scholarly information.

Academic Staff must disclose on a timely basis the creation or discovery of all potentially patentable inventions created or discovered in the course of their University activities or with more than incidental use of University resources. ***Ownership of such inventions must be assigned to the University, regardless of source of funding. The inventor will share in royalties earned. (See Policy on Intellectual Property).***

Academic Staff must disclose in writing to their supervisor, or to the Principal Investigator on their research, whether they (or members of their immediate family) have consulting arrangements, significant financial interests or employment in an outside entity which provides funding (either gift or sponsored), or is otherwise involved in procurement or technology licensing relationships with the UWI.

Faculty should not use University resources as part of their outside consulting activities or for any non-University purpose.

*A conflict of commitment* arises when an individual's outside interests interfere with his/her professional obligations to the University of the West Indies. This produces a conflict of commitment.

With regard to part-time staff the general principle applies to the extent of the appointment. Their other commitments must not interfere with those they have to the University of the West Indies.

Permission for members of the Academic Staff to do consulting, including the reasons for such permission, must be in writing, by the Department Head or by the Principal Investigator. If such permission is granted then the grantor is responsible for ensuring that the consulting activities of the staff member do not adversely impact on the achievement of program or project goals or subject the University to financial risk.

Academic Staff must maintain a significant presence on Campus, consistent with the scope of their employment.

Academic Staff must not allow other professional activities to detract from their primary allegiance to The University of the West Indies. For example, full-time staff must not have significant outside managerial responsibilities nor act as a Principal Investigator on sponsored projects that could be conducted at the UWI, but instead are submitted and managed through another institution. When a staff member is involved with a project where he/she is a co-PI and the protocols differ, then there is need for an amendment to reflect that section of the research which is done by the UWI.

It is the responsibility of each Academic Staff member who wishes to engage in outside consulting to be aware of the University's limits on such activities.

### **Bias /Objectivity**

Bias in this context speaks to possible situations in which one's judgement may be affected by competing interests. This may also be seen, to some extent, as conflict of interest.

If we use the case of a physician who, by virtue of a special interest in a given area develops expertise and engages in research -should that person be allowed to be the caregiver for the person who is a part of the research protocol? Or conversely, should the caregiver be allowed to enroll the patient whose care is their responsibility, in their research project? This would largely depend on the nature of the project. Where the project is independently set up and the management protocols are clearly set out thereby removing individual choice, this seems possible. However, in a situation where individual choice/decision -making is retained, there may well be inherent bias in decision making. This bias would be either for or against the patient, depending on the commitment of the caregiver/ researcher to one or other of their roles. It seems difficult to expect equal commitment but rather a balance between the two which would not necessarily be achievable in individual cases but on the overall picture.

Thus, the individual may suffer although the group as a whole does not. This might well have been operative in the Tuskegee study (apart from other glaring unethical factors), where as clinicians, the information to be gained was very valuable in understanding the disease and therefore to the development of a satisfactory approach to its treatment but there was failure to acknowledge the damage to the individual that was being caused. The bias here would be towards the research and its potential value and would deny the autonomy of the individual.

The clinician/researcher may find it challenging to give complete information to a prospective research subject because the presentation of such complete information might deter the potential subject from agreeing to participate. So it may be necessary to separate the enrolling process from the conduct of the research, thereby removing the clinician/researcher from a possible position of biased influence. Also, the development of the fact sheet containing the information to be shared, would have to be independently developed/approved to ensure full sharing of the true information with the prospective enrollee.

Bias can operate in any area of research, not just the medical. It is relatively easy to arrive at a point where one can not distinguish between the actual results and what one wishes the results to say or reveal. Margins of error can be manipulated and the concept of "rounding up or down" can affect the results of research and ultimately the efficacy and validity of findings. One does not here suggest that this is deliberate. It is mentioned because it is essential that there is awareness of this potential conflict –subconscious at times -so that one can guard against its occurrence.

### **Negligence vs. misconduct**

Academics have a responsibility to themselves, their students, their institution and to the wider public to be honest and fair in their activities, particularly in their research and scholarly conduct. Professional misconduct has very negative effects on the perceived integrity of an institution and its credibility. This in turn can adversely affect the institution's ability to attract funds.

*Trust* -by colleagues and by society in general can not be over-emphasised. As a result of this, some institutions deem it essential to have at least one member of the outside community on their research committees. In medical research it is wise to have more than one such person.

*"Misconduct"* is defined as improper and/or unprofessional behaviour and generally refers to some form of impropriety, blunder or wrong. While not behaviour that is approved of, it tends not to have the serious consequences that "scientific misconduct" has. It can consist of neglecting academic duties; in not indulging in appropriate research to widen the body of knowledge in one's field and so on. These types of misconduct are usually dealt with by the Dean of the relevant Faculty or by the Principal of the Campus.

In some institutions it is referred to as the Fundamental Standard and serious/extreme violations include:

- Physical assault
- Property damage
- Theft
- Sexual harassment

"Negligence" -for example, disregard for accuracy and the inadequate supervision of students etc, -has to be dealt with separately in terms of discipline and is not considered scientific misconduct.

("Honest Error" could be a defence to a charge of negligence).

"*Scientific/academic misconduct*" is defined as fabrication, falsification, plagiarism or other practices that seriously deviate from those commonly accepted within the scientific /academic community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. Also included as "scientific/academic misconduct" for this purpose is retaliation of any kind against a person who, acting in good faith, reported or provided information about suspected or alleged misconduct.

### **Transparency**

Researchers are expected to maintain the highest standards of honesty and integrity. Any form of academic dishonesty is a serious offence.

There is an established principle of "openness" in research and this includes the freedom of access by all **interested** persons to the underlying data, to the processes and to the final results of the research. Except under exceptional circumstances, no programme of research that requires secrecy should be undertaken.

Under no circumstances should a faculty member engage a student in a project governed by an extended publication delay agreement or contractual arrangement that could present a barrier to the timely submission of the student's thesis or dissertation.

The exceptions to the principle of "openness" include the following:

If part of the granting or sponsoring documents establishes that the project is not freely publishable

In a programme of research involving the examination, through interview techniques or otherwise of a living human being, reasonable provision may be made to protect the rights of that individual to privacy

In a programme of research sponsored by an outside entity, provision may be made for a short delay in the publication of research results, for patenting purposes or for sponsor review of and comment on the manuscripts, providing that no basis exists at the beginning of the project to expect that the sponsor would attempt either to suppress publication or to impose substantive changes in the manuscripts.

If, in a programme *of* research, private papers, documents, diaries or analogous materials have been provided to the investigator, provision may be made to preserve the confidentiality *of* those materials for the purpose *of* protecting the individual privacy *of* the author, or *of* his /her immediate family.

No research on a thesis or dissertation should be undertaken if, at the time the topic is set, there is any substantial possibility that it will lead to a secret thesis or dissertation.

### **Deception**

This is the intentional misleading of subjects or the withholding of information about the nature of the experiment.

Ethical concerns are increased when there is deception since, *de facto*, there is no informed consent if there is deception.

Deception is arguably necessary for certain types of behavioural research when full knowledge by the subject might bias the results but it is imperative that subjects be fully debriefed. Subjects must also have the opportunity to withdraw and to have their data removed.

## **Plagiarism**

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 by a researcher of work done by other people must be appropriately and adequately acknowledged.

Plagiarism is an act of academic dishonesty and is considered to be misconduct meriting the most severe disciplinary penalties.

## **Misuse of research funds**

Where a research funding body provides guidelines on the use of research funds, researchers and Principal Investigators must follow those guidelines scrupulously, including adequate reporting of financial statements as required by the sponsor. Researchers and Principal Investigators must also follow all university guidelines on the management and disbursement of funds. Regardless of the source of research funding, it is not permitted to divert research resources for personal use, except in cases where the grant or contract specifically provides otherwise or permission has subsequently been given. Should misuse of research funds occur, offenders will be subject to the disciplinary procedures of the University.

## **Collaborative Research (*inter/intra*)**

### *The Duty on the Parties to Resolve Disputes*

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

Although the University has no legal 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 may help facilitate the resolution of disputes, in accordance with the following provisions: .

If the dispute is between individuals working under a Principal Investigator (s) the Principal Investigator should investigate and attempt to resolve the matter. If

Principal Investigator is involved in the dispute, the Head(s) of the Department(s) or academic unit(s) concerned should investigate and attempt to resolve the matter. If any party involved in the dispute should object to the investigation of a Head, or if a Head is directly involved in the dispute or allegation of misconduct, the Dean of the appropriate Faculty and/or the Pro Vice Chancellor (Research or Graduate Studies) should be informed and may either investigate the dispute and attempt to resolve it or nominate a senior academic staff member, acceptable to the parties, to act as investigator, who would attempt to resolve the matter.

## **Ethical ISSUES for Consideration by the Committee**

### **Assessment of Risks and Benefits**

"Research must be justified on the basis of a favourable risk/benefit ratio. Every...research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subjects or to others. Concern for the interests of the subjects must always prevail over the interests of science and society.

In order to justify exposing subjects to any risks of experimentation, therefore, research must be well-designed and addressing an important question.

The assessment of the potential benefits of research includes estimations of:

- |                                 |   |
|---------------------------------|---|
| <b>The <i>magnitude</i></b>     | How is the knowledge gained likely to be used? In the research of a particular treatment, how severe is the problem which this research aims to alleviate? How common is the problem? |
| <b>The <i>probability</i></b>   | How likely is the research to achieve its aims?   |
| <b>The <i>beneficiaries</i></b> | Is the research intended to benefit the participant or other people?  |
| <b><i>Resources</i></b>         | Will the potential benefits be limited because they are very expensive, or require unusually highly trained professionals?  |

**The assessment of potential harm includes estimations of:**

- |                                  |  |
|----------------------------------|--|
| <i>The types of intervention</i> | How invasive or intrusive is the research? (psycho-social research should be assessed as carefully as physical research)                                       |
| <i>The magnitude</i>             | How severe may be the harms associated with the research procedures?   |
| <i>The probability</i>           | How likely are the harms to occur?   |
| <i>The timing</i>                | Might adverse effects be brief or long-lasting, immediate or not evident until years later?  |
| <i>Equity</i>                    | Are a few subjects drawn into too many projects simply because they are available? Are researchers relying unduly on subjects who already have many problems?" |

One should always be aware that there are risks involved as well in non-medical research. Some of these are:

psychological e.g anxiety, distress, onset of behavioural disorders

social

economic

political

legal e.g. Prosecution and civil /criminal liability

Violation of **Privacy & Confidentiality** can cause harm to families and communities. One must be careful to remove "identifiers" after the research is completed.

"Persons can be wronged even if they are not harmed"

## **BIOMEDICAL RESEARCH**

### *a) Human Subjects*

Research involving human subjects must be carried out in accordance with the highest standards of conduct. It must be conducted in a manner which is ethical (??) and which respects the rights of the persons who are the subjects of the research and in accordance with the ethical Code of the University, rules and guidelines prescribed by research funding bodies and the law in the territories where the research is being conducted.

### **Informed Consent**

#### *The Nuremburg Code*

"The voluntary consent of the human subject is absolutely essential."

By 'voluntary' one means several things. Among them is that the person on whom the research is being done should have the legal capacity to make an informed decision:

There should be no force, fraud, deceit, duress, coercion

The subject should have sufficient knowledge of the subject matter -the nature; the duration; the purpose; the methods and means; the risks; the effect on the person's health.

There should be *respect for persons*.

This means *inter alia* that one should guarantee that each participant understands his role in an experiment. The person must be told that it is a research project -control arm; randomized controlled clinical trial, single or double blind. For example, a "patient" might think he/she is being given a cure rather than a placebo...

*There is thinking now that placebos are contrary to the concept of doing no harm and that where there is an existing medication that has efficacy it must be used. In terms of the 'purity' of the research, arguments can be made that it is better to measure from zero (placebo) to a given point.*

Some of the elements to consider in determining whether a subject should be recruited or whether support mechanisms are appropriate are:

Can the person understand the information?

Can the person retain enough of the information to think the question through?

Is the person **legally** able to give consent?

What are the alternatives to participation for the person? Does the person believe that these alternatives are real?

What are the pressures on the subject to consent or refuse?

NB. A signature on a form is **NOT CONSENT**. It is in the process -the gaining of understanding and agreement -that consent occurs.

## VULNERABLE GROUPS

### 1. **Women as Research Participants**

There has always been some hesitation about the use of women in research! clinical trials particularly if these women were pregnant. The potential risk to the foetus was enough to give pause and almost the only exception was when the women themselves had some serious disease which could benefit from the research.

Eventually the thought also emerged that tests without half the population of the scientific world were skewed and that one could include women if the approach was tailored to their specific needs.

The NIH was also very interested in women being included in research and pondered the questions re how therapies affected men and women differently. Under the NIH Guide, the only reason to exclude women who were pregnant was if there was "compelling" evidence that the study was inappropriate re the health of the subject.

The following policy statement pertains primarily to the inclusion of women as subjects in clinical trials and major portions of the text are presented verbatim as published in the Code of Federal Regulations and the Federal Register (USA). (This policy has been adopted by major universities such as Stanford and it is suggested, should be adopted by the UWI).

### **i. "Pregnant Women as Human Research Subjects**

"In the United States of America Drug research using pregnant women as subjects is governed by federal regulations as follows:

No pregnant woman may be involved as a subject in a human clinical research project unless (1) the purpose of the research is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(Research involving the use of pregnant women as subjects) may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus,

except that the father's informed consent need not be secured if(1) the purpose of the research is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

### **ii. Women of Childbearing Potential as Human Research Subjects**

Women should not be excluded from any phase of research unless the science of the project or the health of the subject will be compromised. Regarding clinical drug research, Phase I, II and III trials should have the proportion of women in the study which at least reflects the proportion of women in the population which will receive the drug when it is marketed, and it should enroll numbers adequate to detect clinically significant sex differences in drug metabolism and response.

#### *Risk to Fertility*

It is expected that experimental subjects will be informed about potential risks to their fertility including the development of any abnormalities or abnormalities in function of reproductive organs as a consequence of the proposed study intervention.

"Where abnormalities of reproductive organs or their function (spermatogenesis or ovulation) have been observed in experimental animals as a consequence of the proposed study intervention, the decision to include patients of reproductive age in a clinical study should be based on a careful risk-benefit evaluation, taking into account the nature of the abnormalities, the dosage needed to induce them, the consistency of findings in different species, the severity of the illness being treated, the potential importance of the drug, the availability alternative treatment and the duration of the therapy. ..

## *Risk to Fetus and/or Infant*

### **1. General Guidelines:**

Appropriate precautions should be taken in research studies to guard against inadvertent exposure of fetuses to potentially toxic agents and to inform subjects and patients of potential risk and the need for precautions. In all cases, the informed consent document and (drug information) brochure should include all available information regarding the potential risk of fetal toxicity. If animal reproductive toxicity studies are complete, the results should be presented, with some explanation of their significance in humans. If these studies have not been completed, other pertinent information should be provided, such as general assessment of fetal toxicity in drugs with related structures or pharmacological effects. If no relevant information is available, the informed consent should explicitly note the potential for fetal risk. ..

### **2. Animal Research**

All animal research must be conducted in compliance with the University's guidelines on the use of animals for research and teaching.

"Animal experimentation is fundamental to the biomedical sciences, not only for the advancement of man's understanding of the nature of life and the mechanisms of specific vital processes, but also for the improvement of methods of prevention, diagnosis, and treatment of disease both in man and in animals. The use of animals is also indispensable for testing the potency and safety of biological substances used in human and veterinary medicine, and for determining the toxicity of the rapidly growing number of synthetic substances that never existed before in nature and which may represent a hazard to health. This extensive exploitation by man of animals implies philosophical and moral problems that are not peculiar to their use for scientific purposes, and there are no objective ethical criteria by which to judge claims and counterclaims in such matters. However, there is a consensus that deliberate cruelty is repugnant"

"A major requirement both of national and international ethical codes for human experimentation, and of national legislation in many cases, is that new substances or devices should not be used for the first time on human beings unless previous tests on animals have provided a reasonable presumption of their safety"

## **BASIC PRINCIPLES**

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 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 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 that would cause pain in human beings cause pain in other vertebrate species, although more needs to be known about the perception of pain in animals.

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.

Where waivers are required, the decisions should not rest solely with the investigators directly concerned but should be made, ...by a suitably constituted review body. Such waivers should not be made solely for the purposes of teaching or demonstration.

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 biomedical purposes. Normally the care of animals should be under the supervision of veterinarians having experience in laboratory animal science. In any case, veterinary care should be available as required.

It is the responsibility of the director of an institute or 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."

**(Council for International Organizations of Medical Sciences (CIOMS),**

**"International Guiding Principles for Biomedical Research Involving Animals (1985) )"**

***NB. The Faculty of Medicine has a Faculty-specific set of Guidelines which should be used by them in conjunction with this Code. The Guidelines are subject to review by the University Research Ethics Committee.***

**SANCTIONS -The Carrying out thereof.**

The gathering and assessing of information in cases of alleged research misconduct can be difficult. The professional reputations of those involved must be protected at all costs -particularly in the situation where it is proved that there was an error.

Evaluations must be objective and unbiased

An "outsider" might be useful in the investigative process

Analysis of real or perceived conflicts of interest among those involved should be done

Anonymity/confidentiality -if so requested, should be guaranteed.

Efforts to "restore" the reputations of the accused should be made if the accusations prove to be baseless.

**Office of Sponsored Research  
Graduate Studies & Research  
2004**

**SUGESTED METHOD OF IMPLEMENTATION OF CODE OF**

**ETHICS**

There should be a **University Research Ethics Committee** which would be the "oversight" committee. The members would serve for a minimum of three (3) years on a rotating basis to ensure that they all do not demit office simultaneously and that there is continuity.

This committee would coordinate the policy, that is, they would see to its monitoring and harmonisation.

Its second function would be that specific University-wide collaborative research projects would go to them at "first instance".

This committee would meet as necessary and "meeting" in this context means having consultation and not necessarily face-to-face. Thus, the committee could meet via Round Robin or teleconference.

Each Faculty should have a Faculty Research Ethics Committee and it is preferable if the Chairman is a non-staff member.

Again the tenure should be for three (3) years.

The "oversight" committee should appoint someone to each Faculty Committee.

The composition of these committees should include senior members of staff (academic or administrative) and there should be approximately 10 members. There must be one from the general public; one member who has a legal background; one who js from the religious fraternity and about three members of staff.

The Chairman is to be elected or appointed on consultation, NOT selected. s/he should not be someone with a vested interest or who could be accused/suspected of conflict of interest such as a Dean.

It is this Faculty Committee which would decide -using the Code -on the ethical appropriateness of the research. There win, however, be a category of research which is perceived to do no harm. This category is subject to "exempt review".

We suggest that this be subjected to a mere administrative process. An Administrator would review all categories and then submit the research which is exempted to the Faculty Research Committee for rubber-stamping.

This "rubber-stamping" would be because the research would have met the criteria that the Faculty itself would have set out. Thus, each Faculty would have to come up with its own criteria bearing in mind the possible "harms":

My suggestion re the next step is:

A letter be sent to the Deans on all the Campuses telling them that there is a Code in draft and asking them to give us their criteria for "exempt review".

The guidelines expected from the Faculties re harm/non-harm are in the following categories:

Consent  
Confidentiality  
Conflict of interest  
Anonymity

A deadline should be given to them and when this step is completed, then the University might wish to start the process of approval/amendment and of setting up its committees.