Guidelines for Preparing Research Proposals: A Handbook by the UWI Ethics Committee

The University of The West Indies, Mona Campus

Contents

Foreword

This toolkit has been prepared with the primary aim of supporting researchers across The University of The West Indies (UWI) and its affiliated institutions in preparing research proposals which meet the required ethical standards of the UWI. This document is also intended to enable the development of high quality research which will drive policy and practice in Jamaica and the wider Caribbean, extending to the global environment.

This document is prepared in two sections.

Section A presents an 'Overview of The UWI Ethics Committee (Mona) and the Ethical Review Process'. This section provides researchers with information on:

a. The structure and function of the Committee
b. Key ethical principles which should be observed in conducting research
c. The process involved in submitting a proposal for ethical review.

Section B provides guidelines on 'Preparing Your Proposal - Important Elements of Quantitative, Qualitative & Evaluation Studies'. This section provides important information on the content and procedures involved in designing a research project, bearing in mind the ethical implications for the study.

The UWI Ethics Committee (Mona) encourages all researchers/investigators to utilize this document and other resources within the University to ensure a successful submission.

Professor Horace Fletcher, Chair, UWI Ethics Committee

Acknowledgements

The UWI Ethics Committee (Mona) acknowledges the contributions of the following members of the Committee to the preparation of this document:

Mrs. Tania Rae, The UWI School of Nursing, Mona

Dr. Jasneth Mullings, Health Research Resource Unit & Co-Chair

Dr. Gilian Wharfe, Department of Pathology & Co-Chair

Professor Jennifer Knight-Madden, Sickle Cell Unit, Tropical Medicine Research Institute

Professor Maria Jackson, Department of Community Health & Psychiatry

Mrs. Douladel Tyndale, Department of Community Health & Psychiatry

Dr. Lisa Lindo, Department of Basic Medical Sciences

Dr. Laurian Young-Martin, Department of Basic Medical Sciences

Dr. Mairette Newman, School of Education

Dr. Trevor Ferguson, Epidemiology Research Unit, Tropical Medicine Research Institute

Ms. Kristin Fox, Sir Arthur Lewis Institute of Social and Economic Studies

Dr. Gillian Mason, Department of Sociology, Psychology & Social Work

Professor Kathleen Coard, Department of Pathology

Your Starting Point

A successful review requires the researcher to demonstrate a clear understanding of the fundamentals of appropriate research design, ethical considerations and proper documentation, whilst paying great attention to detail. This means that the researcher/investigator should have an appreciation of the rudiments of the process, which include the guidelines of the Ethics Committee/Institutional Review Board (IRB) to which the submission is being made, the specific documentation required and timelines for submission.

SOME BASIC TIPS FOR PREPARING & SUBMITTING YOUR RESEARCH PROPOSAL

- ✓ Familiarize yourself with the process of ethical review by your Ethics Committee/Institutional Review Board (IRB)
  - Start by reading the guidelines for submission
  - Ensure that your proposal meets the specified requirements of the Ethics Committee to which it is being submitted
- ✓ Prepare a complete submission
  - Ensure that all required documents are submitted
  - Ensure consistency of content across all the documents
- ✓ Proof-read your research proposal before submission
- ✓ Submit on time! Plan to submit your research proposal at least 3 months in advance of the planned start date of your research project to allow for adequate time to revise and resubmit as necessary.

SECTION A:

OVERVIEW OF THE UWI ETHICS COMMITTEE (MONA) AND THE ETHICAL REVIEW PROCESS

The UWI Ethics Committee (Mona) .....Dr. Jasneth Mullings & Mrs. Tania Rae

The UWI Ethics Committee (Mona) is an independent body currently based in the Faculty of Medical Sciences. The responsibility of the Committee is to ensure the safety of research subjects and the integrity of the research process in which human subjects and animals are involved. The Committee considers the scientific rigour of the methods and procedures used, and the relevant ethical issues. The UWI Ethics Committee (Mona) seeks to ensure that the research conducted within the UWI meets required ethical standards.

Roles & Responsibilities of the UWI Ethics Committee

The roles of the UWI Ethics Committee are to:

1. Review prospectively all research protocols involving human and animal subjects proposed within the UWI or UHWI, or by staff members or students of affiliated or other academic institutions, to ensure that they meet the required ethical and scientific standards;

2. Monitor approved research projects that carry possible and significant risk of harm to research subjects, with the committee being empowered to disallow unacceptable research to go forward;

3. Ensure the humane treatment of animals being used experimentally for research and teaching in accordance with the laws of Jamaica;

4. Examine and make recommendations on research-related ethical problems related to the conduct of academic staff members of the UWI and the UHWI and other staff

members and students of the UWI at Mona and the UHWI; this may extend to other institutions with which the UWI may be affiliated;

5. Provide analysis, where requested, of the research-related ethical aspects of the existing or proposed operations for the UWI or the UHWI;

6. Assist in the development of new institutional policies in areas of research-related need for the UWI or the UHWI.

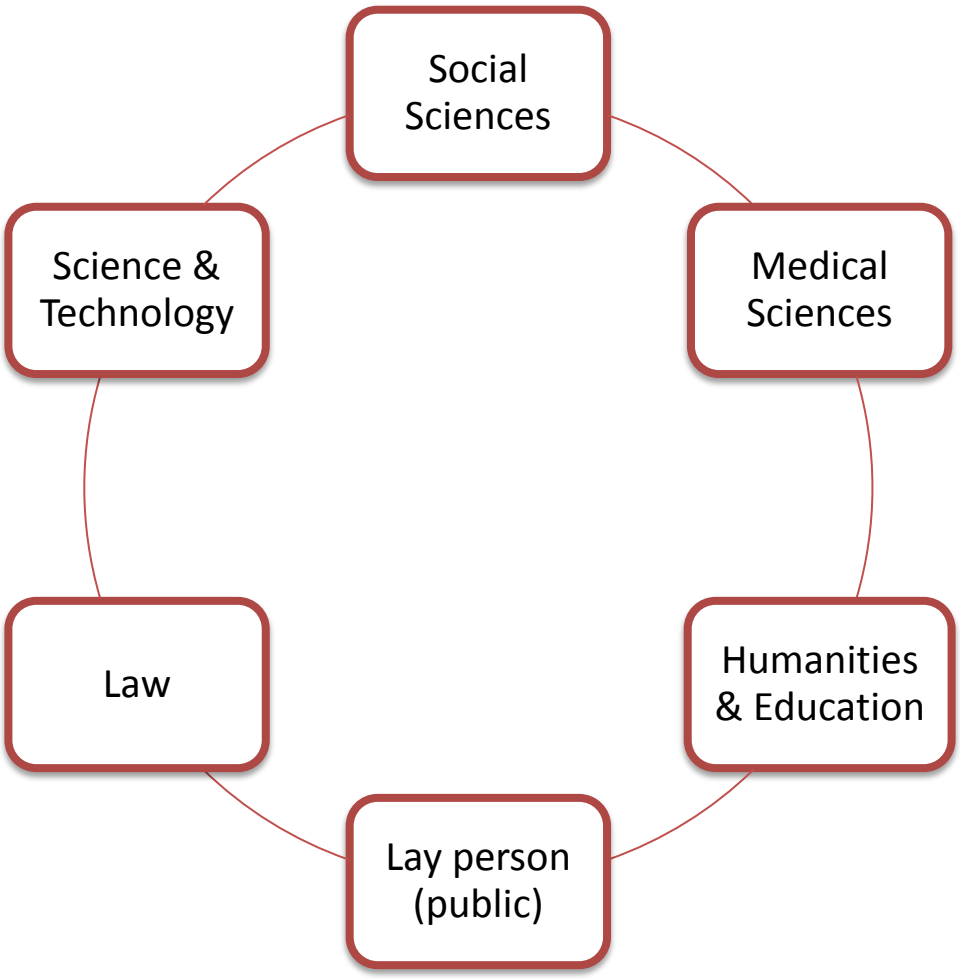
Source: Policy and Procedures on Research Ethics February 2011. The School for Graduate Studies and Research. The University of The West Indies. Retrieved from http://myspot.mona.uwi.edu/fms/sites/default/files/fms/uploads/Ethics%20Policy%20and%20Code%5B1%5D.pdf

Structure of the UWI Ethics Committee

The UWI Ethics Committee (Mona) is comprised of faculty members from professional disciplines in all the faculties across the University and a representative of the public (lay person). Faculty members possess expertise in research and a wide range of academic disciplines. The members of the UWI Ethics Committee (Mona) are required to complete continuing education courses in ethics (e.g. CITI Ethics training programmes) to ensure they are abreast of the current trends in research ethics.

For more information, on the CITI Ethics training programmes, visit:
https://www.citiprogram.org/

Composition of The UWI Ethics Committee (Mona) by Discipline/Faculty



The Process of Ethical Review.....Dr. Gilian Wharfe

Submission & Review Process

Once your proposal is completed, the Principal Investigator should append a cover letter to the Chair of the UWI Ethics Committee (Mona) requesting review. There is a schedule of meetings which will indicate the submission dates (deadlines) for your proposal

Before submitting a proposal for ethical review it is important to ensure that it meets the requirements for review. These include:

Cover letter

- Principal investigator includes a cover letter requesting ethical review and approval.
- In the case of students the Principal investigator is the Supervisor; therefore the letter to the UWI Ethics Committee (Mona) must be written by the Supervisor.

Project Summary/Abstract

- 250 - 300 word summary of the proposal

Proposal

Checklist*

Instrument (s)

Consent forms(s)

Permission to use instruments not in the public domain

Letters of support from [or request to] partner agencies

Project budget

Appendices

For more information visit
http://myspot.mona.uwi.edu/fms/forms-0

*UWI Ethics Committee (Mona) Checklist:

http://myspot.mona.uwi.edu/fms/sites/default/files/fms/uploads/UHWI%20UWI%20FMS%20Ethics%20Committee%27s%20Checklist.pdf

Informed Consent Form - ensure compliance with the requirements of the UWI Ethics Committee:

- If various forms of data collection will be used, there should be a separate and distinct informed consent form for each, for example focus groups and interviews.
- If various groups of persons are included in the study there should be a separate and distinct informed consent form for each, for example participant consent, parental consent & child assent where required
- When it is foreseen that the data (e.g. transcripts) will be used for teaching purposes after the study is completed, this should be explicitly stated in the consent form

http://myspot.mona.uwi.edu/fms/sites/default/files/fms/uploads/INFORMED%20CONSENT%20GUIDELINES.pdf

Instruments – e.g. questionnaires, focus group guide

Copyrighted instruments – letter of permission for use

Recruitment materials (e.g. participant information sheet)

Letters of support/agreement from other agencies which will be involved in the research

Letters to agencies where the data will be collected requesting permission

Photo/Video releases when necessary/relevant

Proposed budget and details

Formatting

Please ensure that you:

- Number all pages of the proposal
- Utilize American Psychological Association (APA) or other accepted referencing formats and that the citation style is correct throughout the document.
- Edit your submission for correct spelling and grammar
- Meet the deadline for submission
- Pay the required fee at the Ethics Secretariat

For more information on the Fee Schedule, visit:
http://myspot.mona.uwi.edu/fms/sites/default/files/fms/uploads/Ethics%20Committee%27s%20Fee%20schedule%5B1%5D.pdf

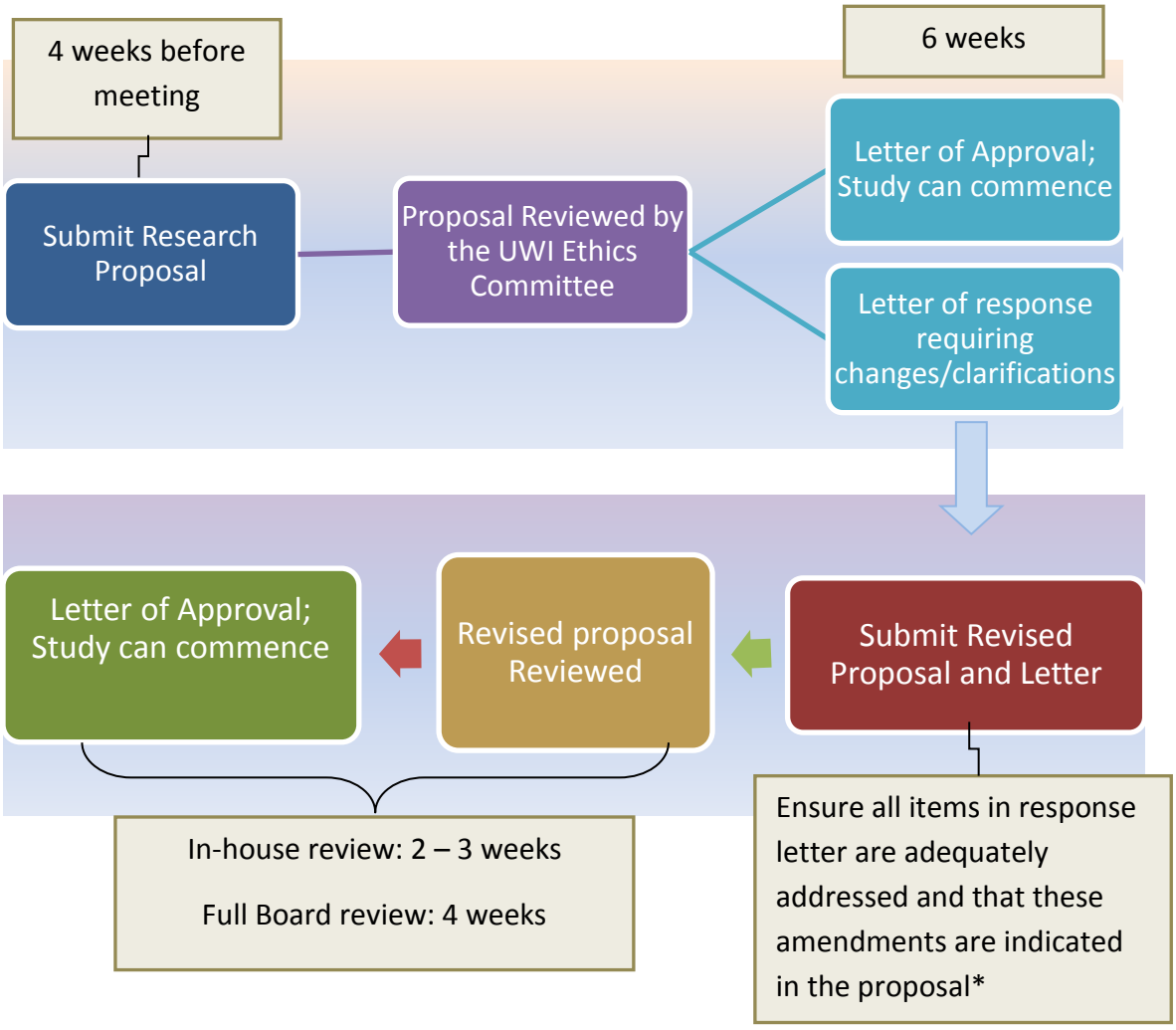
The UWI Thesis Guide is a useful document to guide you in the preparation of your proposal.

For more information on the UWI Thesis Guide, visit:
http://myspot.mona.uwi.edu/postgrad/sites/default/files/postgrad/uploads/thesis_guide.pdf

Summary of the Submission & Review Process

The schema below illustrates the process of submission and review:

Schema of the Submission and Review Process



*Amendments to proposals

- Read the response letter carefully and address each concern indicated in a cover letter to the Chairman of the Ethics Committee. Ensure that you make reference to the relevant section/s in the proposal which has/have been corrected.

Levels of Ethical Review

Full Board Review (studies which qualify):

- Studies on vulnerable populations (e.g. children, pregnant women, inmates, mentally ill, etc.)
- Clinical Trials
- Studies where there is potential for personal identification of participants
- Studies on sensitive issues – e.g. sexuality, socially undesirable behaviors, illegal practices (e.g. illicit drug use)

Exempt from Full Board Review (studies which qualify):

- 'Minimal risk' studies – where the probability of harm or discomfort does not exceed ordinary daily life experiences or during the performance of routine psychological or physical examinations or tests
- Publicly available or wholly de-identified data (e.g. archival data, chart reviews where names are removed; census data, etc.)
- Standard educational tests
- Simple observation of public behavior on public property

Expedited Review (studies which qualify):

- Research which involves minimal risk but does not qualify for exemption from Full Board Review
- Studies in which minor changes have been made to a study which received prior approval(during a one year period)

Exemptions to the Review Process

Grounds for exemption from ethical review can be established in the following instances, provided that no elements of research are entailed:

- Quality assurance studies
- Performance reviews or tests
    - performance assessment of employees within normal requirements
    - educational assessments of students within normal requirements

- Studies on public figures which utilize publicly available information (i.e. public records, documents, archived materials). Special requests to interview public figures or to access private information will however require ethical review.
- Observation of public spaces where participants can be expected to be seeking public visibility (e.g. political meetings, demonstrations)

Research Conducted by UWI Faculty/Students in other jurisdictions

It is expected that studies which involve human subjects or animals, conducted by UWI Mona faculty and students in any jurisdiction, should receive ethical clearance from an approved Ethics Committee/IRB.

Approval by other Ethics Committees/IRBs

Research proposals which have received approval from other Ethics Committees/IRBs may be subject to review by the UWI Ethics Committee. In the event where a study is being submitted for review and has received approval from another Ethics Committees/IRB, evidence of approval should be submitted along with the proposal.

Period of Approval

Researchers should note that approvals are valid for a one year period, after which Continuing Reviews may be required. These reviews will attract an administrative fee. The Ethics Committee reserves the right to apply a waiver of fees as deemed applicable.

The Goals of Research Ethics

Research aims to bring about new knowledge or a deepening of the understanding of a particular phenomenon. Research may involve human subjects, animals, plants or inanimate objects, such as instruments and other devices. Research involving human subjects is of particular importance with regards to securing their protection from harm and ensuring that their human rights are not violated. In a similar vein, animals too require this protection. Research ethics seek to ensure the ethical soundness of the conditions under which participants are engaged. This process should also contribute to providing high quality evidence for policy making and practice across the sciences and professional disciplines.

Codes to protect human subjects

Research ethics have been informed by a number of codes and guidelines which have been established to protect human subjects engaged in research studies. Chief among these are the Nuremburg Code, Declaration of Helsinki, the Council of International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines and the Belmont Report.

- Nuremburg Code - http://www.hhs.gov/ohrp/archive/nurcode.html

QUICK CHECK BOX

Key Ethical Principles Underlying Human Subject Research

- Respect for persons: recognizing that human subjects have the right to personal dignity and autonomy (participants must make an informed choice about participation in research); privacy and confidentiality must be maintained; ensuring that special protection is afforded to those with diminished autonomy (e.g. children, pregnant women, prisoners)
- Beneficence: obligation to protect persons from harm; any anticipated benefits of the study should be maximized, while minimizing any potential risk of harm; what are the benefits and do they outweigh the risks?
- Justice: distributing the benefits and burdens of research fairly within the target population; minimizing respondent burden

Ensure that your research proposal reflects these principles

- Declaration of Helsinki - http://www.wma.net/en/30publications/10policies/b3/
- Belmont Report - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

The UWI Policy and Procedures on Research Ethics – 2011

In its policy statement on Research Ethics, The University of The West Indies lays out its Code of Ethics for Research which is applicable to all persons conducting research at the UWI or any of its affiliate institutions. The Code enunciates the principles of the Belmont Report as well as other established codes governing the practice of research.

Policy and Procedures on Research Ethics February 2011. The School for Graduate Studies and Research. The University of The West Indies. Available at http://myspot.mona.uwi.edu/fms/sites/default/files/fms/uploads/Ethics%20Policy%20and%20Code%5B1%5D.pdf

Ethical Issues in Research……. Dr. Jasneth Mullings

Researchers should be mindful of some factors which may constitute ethical breaches in the research paradigm. These include:

- **Recruitment of subjects**: It is inappropriate to engage persons who are clearly in a position of power over the subject in the recruitment and consent process; examples include teacher, supervisors, attending physicians, or clinicians, who have seniority over the study participant. Such situations provide an opportunity for coercion or undue influence and should be avoided.

Ethical principle: ***Respect for persons***

- **Informed consent**: The researcher should ensure the consent process was duly engaged and that would-be participants are adequately informed about the research process and expected outcomes, while having been given sufficient opportunity to consider their involvement in the research process.

  Ethical principle: ***Respect for persons***

- **Respondent burden:** While subjects should be fairly selected and on the basis of their potential/ ability to contribute to an improved understanding of a phenomenon, every effort should be made to avoid overburdening the respondent. This may occur by way of repetitively targeting a specific population which has been extensively studied in other research projects or it may be via a lengthy research process which may prove inefficient due to the participant having to over-extend him/herself.

  Ethical principle: **Justice**

- **Accessing data/subjects**: Researchers should request permission from the appropriate authorities to access research subjects (i.e. Heads of Departments or agencies where potential participants may be accessed; or institutions where data are available on the study population).

  Ethical principle: **Respect for persons**

- **Duty to assure privacy and confidentiality**: The researcher is duty bound to protect the best interest of the research participant. This includes ensuring privacy of the research process (e.g. location of interview; use of de-identified or anonymized data) and confidentiality in the management of the data (i.e. storage and reporting) (e.g. storage of data in a secure location accessible only to researchers; reporting of results in aggregate form).

  Ethical principle: **Respect for persons**

- **Risks vs. benefits**: The risks and benefits associated with a study should be carefully analyzed to ensure an acceptable risk: benefit ratio. Generally benefits of a study are expected to outweigh the risk. Benefits under consideration should be expressed in terms of their potential to occur (i.e. benefits may accrue to the subject directly (e.g. health assessment or referrals) and may also extend to the community at large (e.g. public health benefit). Where there are no direct benefits to the participant, this should be clearly stated.

Ethical principle: **Beneficence**

- **Referencing**: The appropriate attribution of ideas must be maintained at all times. This requires researchers to ensure that their research proposal reflects the contribution of the relevant authors and sources. Standard citation and referencing formats should be consistently used throughout the document (e.g. APA, Vancouver, or other style as appropriate for the particular discipline under which the study is being submitted).

The University of The West Indies Policy on Graduate Student Plagiarism
http://myspot.mona.uwi.edu/postgrad/sites/default/files/postgrad/uploads/Policy%20on%20Graduate%20Student%20Plagiarism.pdf

- **Plagiarism**: This is an offence which the University takes seriously, with significant consequences. The University uses the plagiarism software Turnitin to review research papers/projects/theses/dissertations. Students can also use this software to check their work against original documents which may have been referenced in their papers.

For more information, visit:
http://www.uwi.edu/qrip/turnitin.aspx

Risks Associated with Research

All research entails some level of risk. Risks involve harm which may be directly related to the procedures of the research, or from processes arising from the conduct of the research (e.g. breach of confidentiality)

Risks may be:

- Physical – such as pain, drug side effects or injury
- Psychological – such as emotional distress arising from disclosure of information during the research process
- Social – such as stigmatization from being associated with a study
- Economic - such as loss of job arising from disclosure of information

In the realm of research, risks may be denominated in one of three categories - minimal, moderate & high. In writing your proposal you will have to identify the level of risk involved considering the following criteria:

Criteria for assessing the level of risk in your study

Risk Level	Study Description	Examples
Minimal	Study poses no more risk than expected in daily life	Recording of data using routine non-invasive tests or procedures (e.g. blood pressure, urine tests physical exam, routine psychological testing) Studies of a non-sensitive nature (e.g. non-interventional studies such as observational studies of behavior ; De-identified chart reviews; publicly available data, educational tests
Moderate	Study represents a slight increase (over minimal) in risk; where the likelihood of serious harm to the subject or the probability of a reversible event of low or moderate severity is low. Procedures must be well described, with a mechanism in place to effectively identify and treat with adverse events	Low risk interventions or invasive procedures akin to those practiced in routine clinical care Studies which investigate sensitive information or which have the potential for a breach of confidentiality Studies in which there is the potential for underlying health conditions of subjects to become aggravated Studies in which safety concerns are minor or for which there is available safety data in humans Minimal risk studies which involve vulnerable populations
High	Study carries a greater than a moderate risk as there is an increased likelihood of a serious adverse event which may result in prolonged or permanent damage to the participant and/or researcher The participant may derive a direct benefit, however risks are high and uncertainty about adverse outcomes may be significant	Investigation/intervention for the prevention or treatment of diseases which may result in irreversible morbidity or death Investigation/intervention involving invasive procedure such as drugs or devices which carry a significant risk of harm Studies which involve the use of new procedures or treatments for which safety data in humans is limited or unavailable

Vulnerable Populations

Vulnerable subjects are persons who may have any of the following features:

- A diminished ability to protect their own interests
- Persons who have a reduced capacity to give informed consent
- Persons who are not able to understand or communicate
- Persons who are not in a position to make a voluntary decision (e.g. facilities where supervisors may have undue influence on participation of research subjects).
- Persons who are at increased risk of harm or increased burden

Persons with the foregoing features may include:

- Prisoners
- Pregnant women
- Children
- Fetuses
- Institutionalized persons
- Armed forces
- Mentally disabled or decisionally impaired persons
- Terminally ill patients
- Persons in dependent positions
- Educationally or economically disadvantaged persons

Source: Ethical Principles and Guidelines for Research Involving Human Subjects – Dr. Georgiana Gordon-Strachan 2011

Informed Consent

Ordinarily, evidence of informed consent by the study participant should be presented in writing. There may however be special situations in which written informed consent is culturally inappropriate or difficult to ascertain. If this is the case, a justification for not obtaining written consent, along with detailed procedures by which participants' consent will be sought should be described in the proposal. The study participant should be provided with a document detailing the information provided during the consent process.

The UWI Ethics Committee (Mona) will consider the justification provided to decide on a waiver of the normal requirements for informed consent [partial or complete waiver].

Animal Subjects……..Dr. Lisa Lindo/Dr. Laurian Young-Martin

Research proposals involving the use of animals should be guided by the same principles for the documentation/preparation of proposals involving human subjects. However, there are key areas which need to be addressed such as:

i) Justification for the number of animals to be used. In justifying the number of animals requested for the study, researchers must consider:

- Replacing animals wherever possible
- Refining the study design or
- Reducing the number of animals to the minimum possible required to achieve the aim and objectives of the study.

QUICK CHECK BOX

Key Principles in Conducting Research on Laboratory Animal Subjects: the 3 Rs

- **Replace** animals wherever possible
- **Refine** the study design
- **Reduce** the number of animals to the minimum possible required to achieve the study aim and objectives

ii) Precautionary measures to be taken where hazardous chemicals, organisms etc. are to be used

iii) Provide a detailed outline of all procedures to be used in the study

Source: The UWI Ethics Committee (Mona) (http://www.mona.uwi.edu/fms/uwi-ethics-committee)

Please note that if the investigator wishes to request additional animals to complete or continue the study, this request should be made to the Ethics Committee with a justification. Additional information on the ethical use and care of animals may be sought in the "Guide for the Care and Use of Laboratory Animals" The National Research Council (NRC), 1996, 6th Edition, National Academies Press, Washington DC. This document is available in the Science Library, UWI, Mona.

To view this document, visit: http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-laboratory-animals.pdf

SECTION B:

PREPARING YOUR PROPOSAL: Important Elements of Quantitative, Qualitative & Evaluation Studies

QUANTITATIVE RESEARCH……

Professor Maria Jackson & Mrs. Douladel Tyndale

i. **Title of the study** should be succinct while clearly and accurately reflecting the aim of the study.

ii. **Summary** should be a brief description of the overall proposal highlighting the main points regarding:

   a. Previous work in the area
   b. Justification for and aim of the study
   c. Methodological approach to be taken (including study design, sampling technique and size, data collection)
   d. Significance of the study
   e. Ethical considerations (institutional permission/approval, informed consent, risks, benefits, confidentiality)

   (*Maximum 300 words for Summary*)

1. **Introduction**:
   a. Literature review should provide a critical appraisal of previously published studies
   b. The rationale/justification should show why the current study is of interest.

QUICK CHECK BOX

Your proposal should capture the following elements:

- Title
- Summary (300 words maximum)
- Introduction /Literature Review
- Aims/objectives
- Methods
  - Study design
  - Sampling
  - Detailed procedures
- Recruitment & consent
- Measurements
- Statistical analyses
- Ethical Considerations
- Limitations
- References
- Relevant appendices

2. **Aims and objectives or research questions** (Hypotheses may be included)
    a. Objectives should be reflected in and be consistent with the instruments to be used
3. **Methods and Materials**
    a. Study design (e.g. cross-sectional, case-control, cohort, randomized controlled trials etc.)
    b. Study population – target group in which the study will be conducted
    c. Sample – subset of the study population which will actually be involved in the study
    d. Conceptual definition of variables and operationalization of variables (i.e. what they are and how they will be measured)
    e. Inclusion and exclusion criteria
    f. Sampling
        i. Technique (e.g. probability proportionate to size, systematic, incidental, random etc.)
        ii. Size (state assumptions for determination of sample size and number of persons to be studied)
    g. Procedures for recruitment and consent
        i. Who will inform the target population of the study?; who will seek consent?; when & how this will be done

            NB: if the researcher is in a position of power with respect to the potential subject, recruitment and consenting procedures should be undertaken by an independent party (e.g. of positions of power which could be perceived as coercion include clinicians providing care to a patient; teachers seeking consent for students to participate in their own study).
    h. Data collection
        i. Procedures (detail the approach to obtaining data including how measurements will be conducted and by whom)
        ii. Instruments (e.g. questionnaires, data extraction forms)

NB: Where standardized instruments are used, evidence of permission for use and instrument validity and reliability must be submitted

iii. Measurements (e.g. anthropometry, clinical measurements)

i. Statistical analyses
    i. Software to be used
    ii. Descriptive e.g. summary statistics (mean and standard deviation, median and interquartile range, percentage etc.), bivariate relationships e.g. chi-square, t-tests, ANOVA (or non-parametric equivalents) etc.
    iii. Inferential e.g. correlations, regressions (linear, logistic etc.)

j. Data handling and record keeping (storage-who, where, duration)

4. **Ethical considerations – Ethical Issues in Research**
5. **Limitations** – factors which may limit reliability, validity or generalizability of study findings (e.g. limited participation, use of non-probability sampling techniques, loss to follow-up for cohort studies)
6. **References** – ensure use of appropriate style and consistency with style
7. **Appendices** – any materials of relevance to the proposal – e.g. instruments, forms, letters

A Randomized Control Clinical Trial is a study in which the researcher is manipulating the exposure (s) of participants and measuring outcomes. Participants are randomly assigned to a study group (also referred to as study arm). These study arms represent 'treatment' and 'control' groups which are compared to examine the outcome of interest.

The Consolidated Standards of Reporting Trials (CONSORT) represents a number of initiatives aimed at improving the reporting of randomized controlled trials. Developed by the CONSORT Group useful resource materials are provided in the Consort 2010 Key Documents:

- The CONSORT 2010 Statement
- The CONSORT 2010 Checklist
- The CONSORT 2010 Flow Diagram
- The CONSORT 2010 Explanation and Elaboration (E&E) Document

Consolidated Standards of Reporting Trials
http://www.consort-statement.org/

Key Principles

- Describe the subject selection process in detail
- Describe the randomization process
- Provide a consort diagram
- Specify inclusion and exclusion criteria
- Indicate level (s) of blinding
- Specify outcome measures
- Statistically determine the minimum number of participants per group to enable a robust analysis; a power analysis is useful
- Describe data analysis methods – e.g. intent to treat; number needed to treat; per-protocol analysis
- Describe measures to monitor and report on loss to follow-up; seek to minimize loss to follow-up
- Describe ethical considerations
- Describe the monitoring mechanism to be established to ensure patient/subject safety (e.g. Data Safety Monitoring Board)
- Describe methods to identify and report on adverse events

OTHER USEFUL SITES:

- **Clinicaltrials.Gov - Learn About Clinical Studies**

  http://clinicaltrials.gov/ct2/about-studies/learn

- **National Institutes of Health (NIH) Clinical Research Trials and You**

  http://www.nih.gov/health/clinicaltrials/

- **Medlineplus® Clinical Trials Information**

  http://www.nlm.nih.gov/medlineplus/clinicaltrials.html

Here are some other useful checklists which may assist you in planning your study:

CONSORT Consolidated Standards Of Reporting Trials
Full Record | Checklist | Flow Diagram

STROBE Strengthening the Reporting of Observational studies in Epidemiology
Full Record | Checklist

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses
Full Record | Checklist | Flow Diagram

STARD Standards for Reporting Studies of Diagnostic Accuracy
Full Record | Checklist | Flow Diagram

COREQ Consolidated criteria for reporting qualitative research
Full Record

ENTREQ Enhancing transparency in reporting the synthesis of qualitative research
Full Record

SQUIRE Publication guidelines for quality improvement in health care
Full Record | Checklist

CHEERS Consolidated Health Economic Evaluation Reporting Standards
Full Record | Checklist

CARE Consensus-based Clinical Case Reporting Guideline Development
Full Record | Checklist

SAMPL Basic Statistical Reporting for Articles Published in Biomedical Journals: The "Statistical Analyses and Methods in the Published Literature"
Full Record

UWI Clinical Trials Centre

The University of The West Indies has established a Clinical Trials Centre which supports investigators in protocol development, budgeting, ethical guidelines, data management and reporting. Located in the Faculty of Medical Sciences, the Clinical Trials Centre provides standardized operating procedures (SOPs) for initiating, conducting and completing clinical trials.

All clinical trials must be registered with the Clinical Trials Centre.

The primary responsibilities of the Clinical Trials Centre are to:

- Coordinate clinical trials conducted in the Faculty of Medical Sciences.
- Establish SOPs for the administration of the trials.
- Create an efficient system for the initiating and implementing of clinical trials within the project time lines.
- Provide support to ensure that all trials are conducted in accordance with the highest ethical standards and clinical practices.
- Provide support to ensure that all contractual, budgetary, regulatory and legal requirements are satisfied.
- Ensure that the University's earnings from these projects are maximized.

Source: The UWI Ethics Committee (Mona) (http://www.mona.uwi.edu/fms/uwi-ethics-committee)

Registration of Clinical Trials

Investigators who are developing protocols for clinical trials should consult the Clinical Trials Centre to have the trials registered. Registration is a legal requirement as well as a condition for the publication of research results by the International Committee of Medical Journal Editors (ICMJE).

For more information, visit:
Clinical Trials Centre UWI Mona at http://myspot.mona.uwi.edu/fms/clinical-trials-centre

AND

ClinicalTrials.gov at http://clinicaltrials.gov/ct2/manage-recs/background#WhyRegister

QUALITATIVE RESEARCH.....Mrs. Tania Rae, Ms. Kristin Fox & Dr. Gillian Mason

For qualitative research, the following may guide you:

1. **Introduction:**
   - The philosophical or theoretical underpinnings are stated.
   - A summary of the literature review that provides a justification for conducting the proposed study.
   - Purpose of study – is it discovery, description, conceptualisation, sensitisation, emancipatory?
2. **Research question:** It should be explicitly stated.

Ask yourself: "Is this question relevant?"

   - A relevant question is justified and linked to the existing knowledge (empirical research, theory, policy)

3. **Methodology:**

First consider: Is/are the qualitative method(s) appropriate to answer the question (s)?

- Describe the study design and justify it. Explicit details about design and methods should be provided, without limiting the project's evolution

The most common approaches to qualitative research are:

- Case Study
- Narrative Inquiry
- Phenomenology
- Ethnography
- Grounded theory

QUICK CHECK BOX

Qualitative Studies should include the following elements:

1. Introduction:
2. Research question (s):
   - Main question
   - Sub-questions
3. Methodology
   - Case Study Research
   - Narrative Inquiry
   - Phenomenology
   - Ethnography
   - Grounded Theory
4. Sampling
5. Recruitment
6. Data collection
7. Data analysis
8. Ethical considerations
9. Limitations
10. References
11. Relevant appendices

These are the definition of study designs as cited in Brians, Willnat, Manheim & Rich, (2010).

Case Study

The case study approach is appropriate if distinct cases (e.g., individuals, organisations, events) exist and an in-depth understanding of a case or comparison across cases is desired. It entails exploring a "bounded system (a case) or multiple bounded systems (cases) over time, through detailed, in-depth data collection involving multiple sources of Information" (Creswell, 2006). The final report includes a description of the case and the development of case-based themes.

Narrative Inquiry

Narrative inquiry uses field texts, such as stories, autobiography, journals, field notes, letters, conversations, interviews, family stories, photos (and other artifacts), and life experience, as the units of analysis to research.

Phenomenology

Carpenter (2007) defines phenomenology as "a science whose purpose is to describe a particular phenomenon or the appearance of things, as lived experiences" (p. 43). Topics which are relevant to the lived experience of the subject are appropriate for phenomenological research.

Ethnography

Ethnographic studies immerse the researcher into the culture and life of the subjects being studied in order to describe and learn the culture (Spradley, 1979). It involves data collection methods such as participant observation.

Grounded Theory

This type of qualitative research allows the researcher to develop a theory from the data (Glaser, 1998; Glaser & Strauss, 1967). It is based on an appreciation that research can assist in unearthing an understanding of the commonality of/shared experiences of persons on a particular subject matter.

Sampling:

- What is the setting in which the study will take place?
- What is the population?
- Participants: are they the most appropriate to provide access to the type of knowledge that the researcher is seeking to generate?
- Sampling method -
    - Procedures for sample selection should be described and a justification provided
    - An estimate for sample size should be included with a rationale provided.

Recruitment:

- What is the procedure that will be followed to select the participants?
- Provide details of how the recruitment will take place and by whom
- Assumptions and biases should be clearly stated
- What sampling method am I using? Why?
- For observation - how are the situations that are to be observed selected?

4. Data collection:

- Provide a detailed plan for data collection
- Explain why a particular method of data collection (e.g. focus groups, interviews, observations, document review, and audio-visual material) was chosen.
- If you are observing are you using a checklist?
- Setting
- Time frame
- Who will collect data? If it is the researcher: Is there any conflict of interest?
- Research assistants: Are they linked to the populations? Will the RA be trained for data collection?
- Present and discuss the interview guide/other data collection instrument(s) or the focus group leading questions: How were they developed?
    - Rigour: In qualitative research the term *Trustworthiness* is the overarching concept for rigour and is equivalent to “Internal validity” for quantitative studies.

Trustworthiness has four components - *Credibility*, *Transferability*, *Dependability*, and *Confirmability* respectively. There are specific procedures in qualitative research to ensure that these requirements are met and they should be clearly explained in the methodology.

- Instruments
    - Instruments chosen must be suitable for collecting the appropriate data to answer the research question or address the specific objectives
    - Observations – what are you observing for (i.e. behaviour) and are you using a checklist (e.g. performance)?
    - Interview guides – e.g. questions and prompts
    - Focus group guide – e.g. questions and prompts
    - Document review – e.g. checklist
    - Audio-visual materials - photos, videos, etc.

5. Data analysis:

- Analytical methods should be described. How will data be reduced and analysed? For example, two approaches are Grounded Theory and Framework Analysis. Some of the techniques that are commonly used in data reduction and analysis are: coding, reflective remarks, developing propositions themes, etc. This should be clearly described.
- <u>If pre-existing themes will be used</u>, a rationale for their development and/or selection should be described
- Provide the name of any software that will be used to manage and reduce and organize data
- How will data be stored?
- Who will keep the data stored?
- Where?
- How long will the data be kept?
- How and when will it be destroyed?

6. Ethics:

- Describe how you will comply with the legal and ethical requirements to conduct the study.
- Evidence of approval or attempts to seek approval from any relevant authority
- Process for obtaining informed consent from participants.
- Justification for oral informed consent if that approach will be used,
- Right to refuse and withdraw; benefits to participants, compensation, etc.

7. Limitations:

Limitations may decrease the generalizability of the findings of the study; therefore it is important that the researcher states the theoretical and methodological limitations of the proposed study.

EVALUATION STUDIES……..Mrs. Tania Rae & Dr. Mairette Newman

Some research proposals are **Evaluation Studies.**

An evaluation is:

- The establishment of criteria against which a programme, policy or intervention will be judged as well as the standard against which it will be judged.
- "The process of determining the worth or significance of an activity, policy, or programme"
- An assessment, as systematic and objective as possible, of a planned, on-going, or completed intervention (Organization for Economic Co-operation and Development (OECD) as cited in Morra Imas & Rist, 2009).

Ethical considerations:

- Just as with research, evaluations must be "*designed, conducted and reported in a manner that respects the rights, privacy, dignity and entitlements of those affected by and contributing to the evaluation"(*Australasian Evaluation Society, 2006)
- Do you need ethical approval? Well, it depends on:
  - the purpose of the evaluation
  - the intended use of the data collected
  - the type of data that you will be collecting

Quality review and quality assurance studies may not need ethical approval.

QUICK CHECK BOX

Steps in the Evaluation Process:

1. Plan the evaluation
   - Clarify purpose and scope
2. Design the evaluation
   - Use the Design Matrix
   - Develop evaluation questions
     - Descriptive
     - Normative:
     - Cause-and-effect
   - Select an appropriate methodology
     - Quantitative
     - Qualitative
3. Conduct the evaluation
4. Report evaluation findings
5. Disseminate findings

Where to start?

There are 5 steps in the Evaluation Process:

1. Planning for or scoping the evaluation
2. Designing the evaluation
3. Conducting the evaluation
4. Reporting the evaluation findings
5. Disseminating and following up on evaluation findings (Morra Imas & Rist, 2009)

Preparing an Evaluation Plan

- Describe context and background of the programme or policy
- Identify evaluation purpose and objectives
- Identify and meet with key stakeholders
- Define the evaluation issue and questions
- Describe the evaluation methodology
- Outline team roles and responsibilities
- Map out your plans for dissemination and for reporting
- Prepare a budget for your evaluation
- Plan the timeline and the milestones (IDRC, 2004)

Planning for the evaluation:

Purpose: needs assessment, formative evaluation, summative or some combination; as well as the intended uses of the evaluation's findings.

*C*learly define the purpose:

- What is being evaluated?
- How will the evaluation results be used?
- What type of evaluation will be used?

Designing the Evaluation:

A Design Matrix is a useful tool in this step. It organizes questions and outlines how you will answer those questions (the plans for data collection and analysis) (IPDET, 2009) Therefore, a Design Matrix is basically a breakdown of the methodology for the study

What does a Design Matrix include?

- Evaluation issue
- Evaluation questions and sub-questions (the sub-questions will be the study questions)
- Selected measures for each question or sub-question (how will the variables be measured?)
- Sources of data for answering each question or sub-question (i.e. from participants – e.g. through questionnaires, interviews, observations; from the dockets – e.g. quality assurance documents, incident report forms).
- Appropriate design for each question or sub-question (the methodological design: e.g. cross-sectional, quasi-experimental)
- Data collection strategy:
  - instruments and sampling methods for each question or sub-question
- Develop a data analysis strategy
- Determine the timeline and the budget (Morra Imas & Rist, 2009)

This is a sample of what a Design Matrix may look like. In this case the objective was to conduct a formative evaluation of the implementation process for the "Occupational Exposure Policy" at a particular organization.

QUESTIONS	SUB -QUESTIONS	TYPE OF [SUB]QUESTION	MEASURES OR INDICATORS	TARGET OR STANDARD (if normative)	BASELINE DATA?
1. Is there a reporting system in place for occupational exposure in the organization?	1. What is the incidence of occupational exposure among workers at the organization?	Descriptive	Occupational Exposure Report Log	N/A	Yes. Data from the previous 5 years before implementation of the policy is available for comparison.
	2. Are the incidents of occupational exposure reported within the stipulated time frame?	Normative	Occupational Exposure Report Log	All cases have been logged and reported within the stipulated timeframe.	Yes
2. Are there procedural steps in the management of the occupational exposures adhered to at the organization?	3. Are the exposure report forms completed and submitted as per policy?	Normative	Occupational Exposure Report	The reports for all cases are complete and accurate. The reports have been submitted to the relevant persons/departments.	Yes
	4. Is the risk assessment completed as per policy?	Normative	Risk Assessment Report	Risk assessment reports have been completed.	Yes
3. Is there follow-up care of workers exposed as per policy?	5. Is post exposure counseling conducted as per policy?	Normative	Occupational Exposure Report	All workers exposed received the counselling as outlined by the policy.	Yes
	6. Do workers receive prophylactic medication as per schedule?	Normative	Occupational Exposure Report	All workers have received the post-exposure prophylaxis as per policy. In case of not receiving it, clearly document reason (justified).	Yes

Study Design to answer each question	Sources of Data	Sample	Data collection instrument	Methods of data analysis	COMMENTS
1.Cross sectional	Occupational Exposure Report Log	Incidents recorded in report books during (Specify time period)	"Occupational Exposure report Auditing Tool"	Descriptive statistics	Note trends and display in a chart.
2. Cross sectional	Occupational Exposure Report Log		"Occupational Exposure report Auditing Tool"	Content analysis	Note time frame for reporting and compare to previous years. Cross tabulations for presentation.
3. Cross sectional	Occupational Exposure Report Log	Occupational Exposure Report from (specify time frame)	"Occupational Exposure report Auditing Tool"	Content analysis	Note completeness and accuracy of reports.
4. Cross sectional	Risk Assessment Report		"Occupational Exposure report Auditing Tool"	Descriptive Statistics and Content analysis	Cross tabulations for presentation.
5. Cross sectional	Occupational Exposure Report	Occupational Exposure Report from (specify time frame)	"Occupational Exposure report Auditing Tool"	Descriptive Statistics and Content analysis	Note adherence to schedule. Note any deviations. They should be well justified, documented and followed up.
6. Cross sectional	Occupational Exposure Report		"Occupational Exposure report Auditing Tool"	Descriptive Statistics and Content analysis	Note timeframe, number of sessions, location and counselor

What is an Evaluation Question?

Similar to research questions, an evaluation question is a critical element that gives direction to the evaluation and the evaluation design selected (Morra Imas & Rist, 2009)

- Sources of evaluation question:
  - Questions, concerns, and values of stakeholders
  - Evaluation models
  - Frameworks and approaches, including heuristic (trial and error)

- Existing research and evaluation findings and important issues raised in the literature (Morra Imas & Rist, 2009).

Developing Good Evaluation Questions:

First identify the major issues being addressed by the project, programme or policy. Then decide:

What questions will determine whether those major issues have been affected by the project, programme, or policy you will evaluate? (Morra Imas & Rist, 2009).

Types of Evaluation Questions:

There are 3 main types of evaluation questions: Descriptive, Normative, Cause and effect.

Descriptive: evaluation questions seek to determine what is happening, what is the current situation. For example:

- What is the incidence of occupational exposure among workers at the organization?
- Did programme participants increase their knowledge of HIV prevention methods?

Normative: evaluation questions compare the current situation to a specific target, goal, or benchmark. For example, in the Occupational Exposure Policy example, a question was:

- Is there follow-up care of workers exposed as per policy?

Cause-and-effect: evaluation questions measure what difference the programme or policy or intervention has made, for example:

"As a result of the job training programme, do participants have higher paying jobs that they otherwise would have?" (IPDET, n.d.; Morra Imas & Rist, 2009).

Develop specific **sub-questions** that will help you answer these main evaluation questions. These are going to be the questions that the study will answer. For example in the case of the normative question given in the example above, several sub-questions should be developed. One example is the sub-question about counselling, which is part of the management of occupational exposures. Therefore the evaluator must look at the policy and clearly specify key elements such as: the timeframe when the counselling should take place, the number of counselling sessions and the characteristics of the counselling session (e.g. where it should be done and by whom) in order to assess if the counselling is being done "as per policy".

Similar to a research project you will then describe your **methodology.** All of these can be outlined in the Matrix.

- Which methodology will be used to answer each question?
- Is it going to be a qualitative approach?
- Is it going to be quantitative study?
- Having selected the appropriate methodology, follow the appropriate steps.
- Important questions: What is your sample? What are your sources of data? Are you going to interview individuals? Do you need to design a Data Extraction form? What type of statistic tests will you conduct?

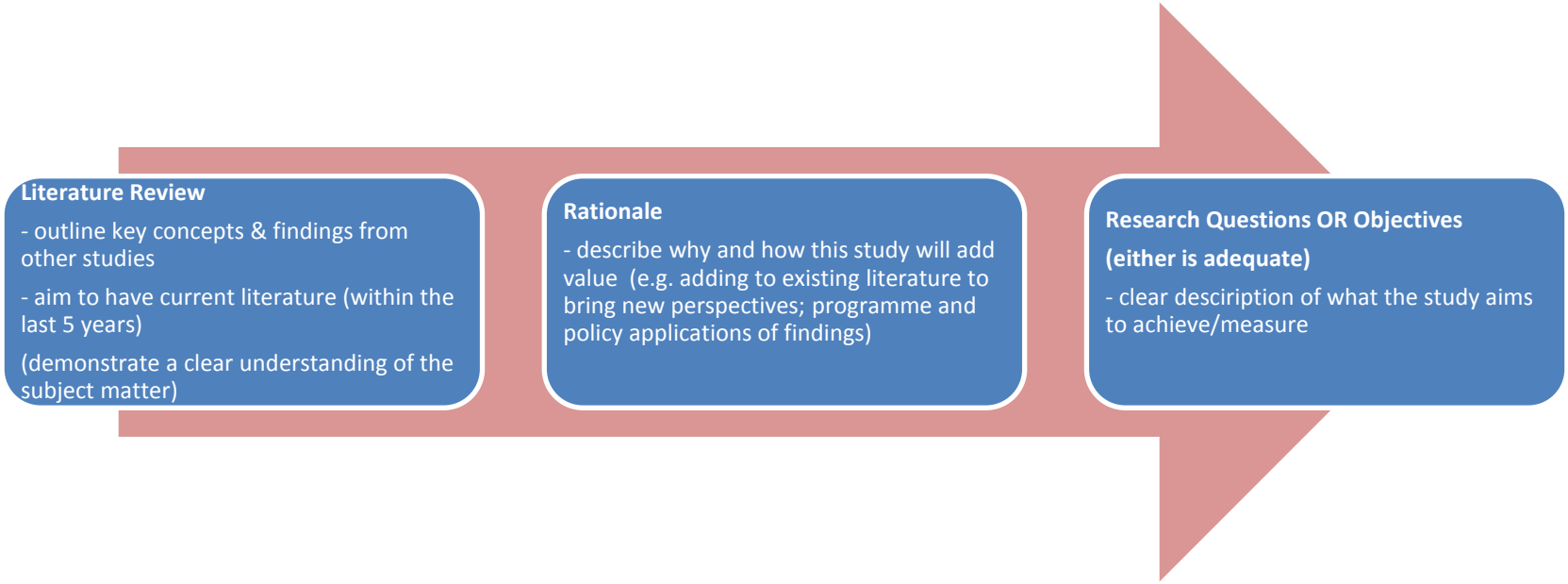
A Summary Guide to Preparing Your Proposal……Dr. Jasneth Mullings

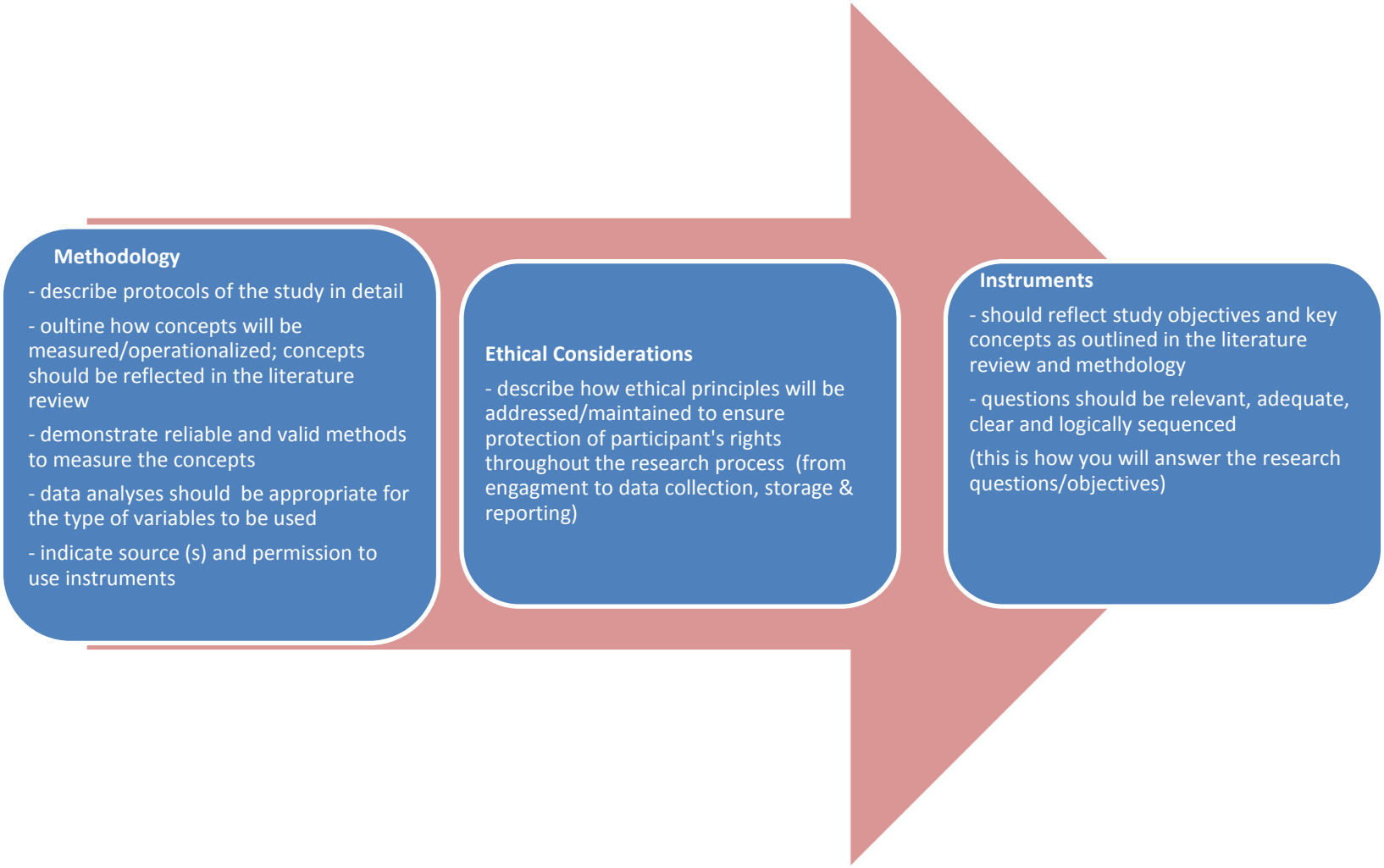
The Proposal as a Research Plan

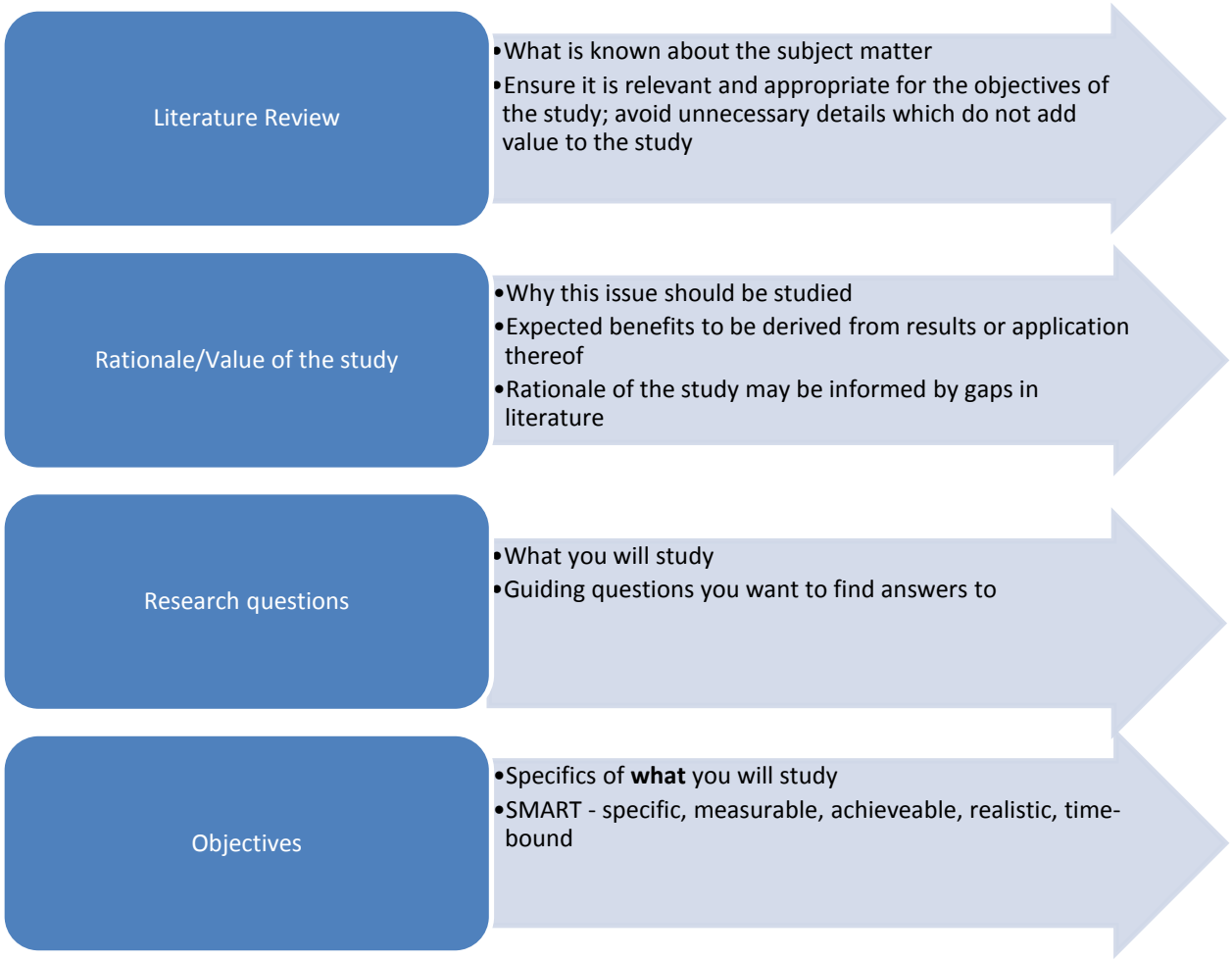
Your research proposal is your template for the research activity. It should speak for itself, allowing the reader to get a clear understanding of the issue you propose to study, its relevance and the methods/protocols you will utilize to answer the research objectives.

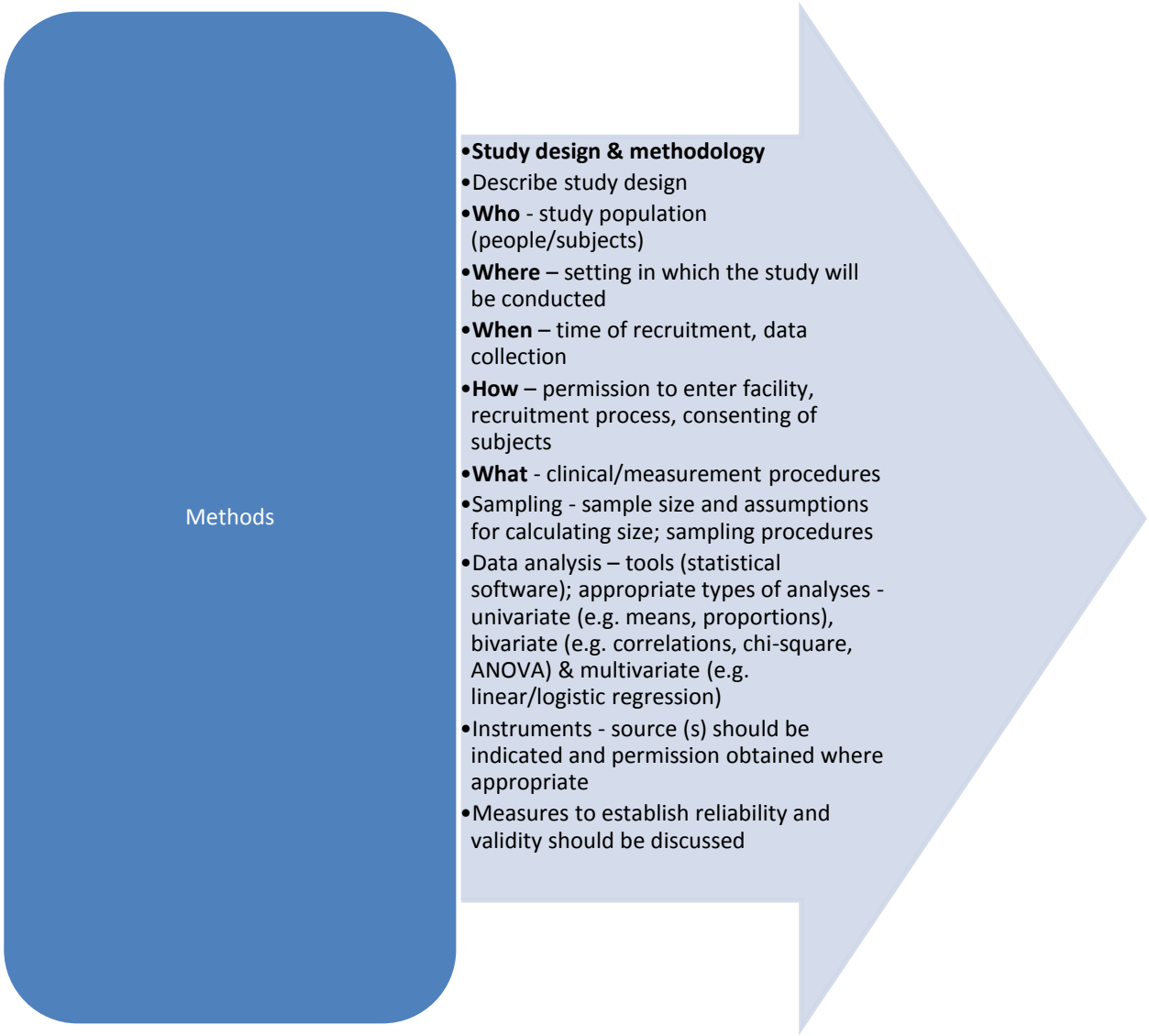
The proposal should read as a plan. There is a common thread which connects all aspects of the plan. Each aspect of the proposal should complement the other aspects of the plan. The proposal must always be stated in the future tense (i.e. what will be done, how it will be done and with whom).

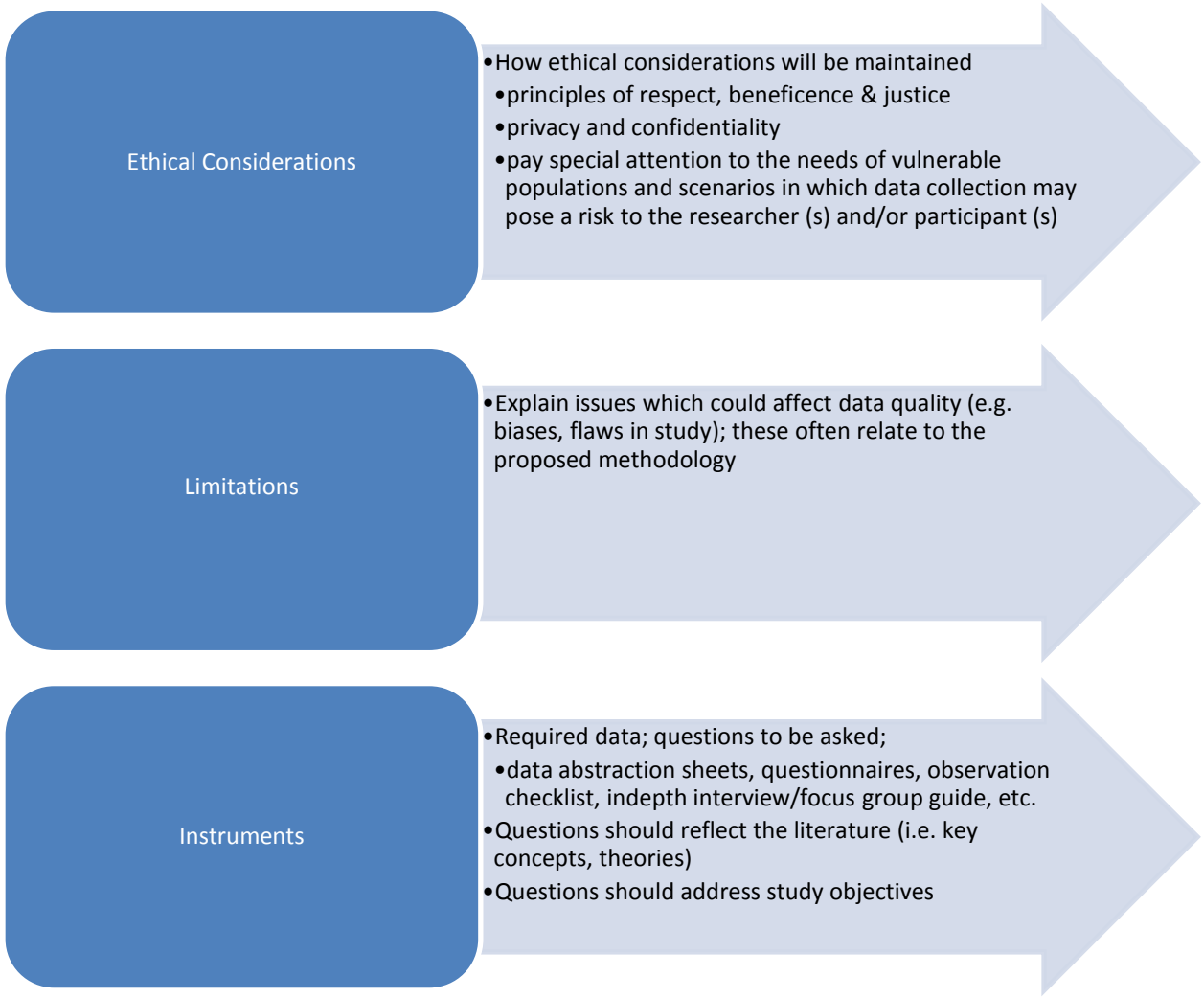
Key Considerations for the Research Proposal & Common Threads




Methodology
- describe protocols of the study in detail
- oultine how concepts will be measured/operationalized; concepts should be reflected in the literature review
- demonstrate reliable and valid methods to measure the concepts
- data analyses should be appropriate for the type of variables to be used
- indicate source (s) and permission to use instruments
Ethical Considerations
- describe how ethical principles will be addressed/maintained to ensure protection of participant's rights throughout the research process (from engagment to data collection, storage & reporting)
Instruments
- should reflect study objectives and key concepts as outlined in the literature review and methdology
- questions should be relevant, adequate, clear and logically sequenced
(this is how you will answer the research questions/objectives)


Literature Review
•What is known about the subject matter
•Ensure it is relevant and appropriate for the objectives of the study; avoid unnecessary details which do not add value to the study
Rationale/Value of the study
•Why this issue should be studied
•Expected benefits to be derived from results or application thereof
•Rationale of the study may be informed by gaps in literature
Research questions
•What you will study
•Guiding questions you want to find answers to
Objectives
•Specifics of **what** you will study
•SMART - specific, measurable, achieveable, realistic, time-bound


Methods
•Study design & methodology
•Describe study design
•Who - study population (people/subjects)
•Where – setting in which the study will be conducted
•When – time of recruitment, data collection
•How – permission to enter facility, recruitment process, consenting of subjects
•What - clinical/measurement procedures
•Sampling - sample size and assumptions for calculating size; sampling procedures
•Data analysis – tools (statistical software); appropriate types of analyses - univariate (e.g. means, proportions), bivariate (e.g. correlations, chi-square, ANOVA) & multivariate (e.g. linear/logistic regression)
•Instruments - source (s) should be indicated and permission obtained where appropriate
•Measures to establish reliability and validity should be discussed


Ethical Considerations
•How ethical considerations will be maintained
•principles of respect, beneficence & justice
•privacy and confidentiality
•pay special attention to the needs of vulnerable populations and scenarios in which data collection may pose a risk to the researcher (s) and/or participant (s)
Limitations
•Explain issues which could affect data quality (e.g. biases, flaws in study); these often relate to the proposed methodology
Instruments
•Required data; questions to be asked;
•data abstraction sheets, questionnaires, observation checklist, indepth interview/focus group guide, etc.
•Questions should reflect the literature (i.e. key concepts, theories)
•Questions should address study objectives

Frequently Asked Questions …… Dr. Jasneth Mullings

1. **Why is ethical approval necessary for a study?**

   Ethical approval assures the researcher, the affiliated institution (s) and potential participants that the proposed study meets internationally acceptable ethical standards for conducting research.

2. **What kinds of studies require ethical approval?**

   All studies which entail contact with human subjects or animals are subject to ethical approval.

3. **Which studies qualify for Expedited vs. Full Board review?**

Full Board Review (studies which qualify):

- Studies on vulnerable populations (e.g. pregnant women, children, inmates, mentally ill, etc.)
- Clinical Trials
- Studies where there is potential for personal identification of participants
- Studies on sensitive issues – e.g. sexuality, socially undesirable behaviors, illegal practices (e.g. illicit drug use)

Exemption from Full Board Review (studies which qualify):

- Minimal risk studies – where the probability of harm or discomfort is not greater than that ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests

Expedited Review (studies which qualify):

- Studies which involve the use of publicly available or wholly de-identified data (e.g. archival data, chart reviews where names are removed; census data, etc.)
- Studies which involve the use of standard educational tests
- Studies which involve simple observation of public behavior on public property
- Research which involves minimal risk but does not qualify for Exemption from Full Board Review
- Studies with minor changes to previously approved research (during a one year period)

4. **How often are Committee meetings held?**

   The UWI Ethics Committee (Mona) meets once monthly (excepting in August.)

5. **How long does it take to get feedback on my proposal?**

   The Committee aims for a turn-around time of 6 - 8 weeks for Full Board reviews and 2 - 3 weeks for Expedited reviews.

6. **How is the feedback on my proposal communicated?**

   Feedback is initially communicated via email, followed by a hard copy of the approval letter. **Approvals are valid for a one year period**.

7. **If I am a student can I be the Principal Investigator of my study?**

   Student researchers are under the guidance of Research Supervisors who will act as Principal Investigators on such studies. As such, the application letter should be submitted under the signature of the Research Supervisor/Principal Investigator.

8. **If I am a student, how will I receive feedback on my study?**

   Feedback will be sent to the Research Supervisor/Principal Investigator. The student may however request a copy.

9. **What is risk?**

   In research, risk relates to the level of harm which may come to a researcher, institution or participant during the research process. The observation of ethical procedures aims to minimize the potential risk to all parties.

10. **How do I know what level of risk applies to my study?**

    A careful analysis should be conducted to determine the level of risk. Further guidance is provided in Criteria for assessing the level of risk in your study .

11. **Where and how should I submit my application?**

    Your application should be submitted to the UWI Ethics Committee (Mona) Secretariat. Your application should be sent electronically to ethics.committee@uwimona.edu.jm and a hard copy submitted to the Secretariat which is located on Block A, FMS Teaching & Research Complex - 2nd floor.

12. **Who should my proposal application be addressed to?**

    Your proposal should be addressed to Professor Horace Fletcher, Chair, UWI Ethics Committee (Mona).

13. **What if I do not agree with comments made by the Ethics Committee?**

    If you disagree with or need clarification on any point (s) raised by reviewers, you may state the grounds of your disagreement/request clarification in your resubmission. Due consideration will be given to issues which are appropriately justified.

14. **What is the process for making a resubmission once corrections have been made?**

    You should provide a letter outlining each amendment/correction made to the proposal. The sections/pages of the revised proposal which highlight the amendments made should also be submitted.

15. **How can I follow up on the progress of my submission?**

    You may contact the UWI Ethics Committee (Mona) Secretariat at ethics.committee@uwimona.edu.jm or telephone 970-4892 or 927-2556.

If you have any other questions, you may contact the UWI Ethics Committee (Mona) Secretariat at ethics.committee@uwimona.edu.jm or telephone 970-4892 or 927-2556.

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