NORTHERN CARIBBEAN UNIVERSITY
OFFICE OF RESEARCH AND GRANTS

RESEARCH POLICY AND PROCEDURES MANUAL

NCU Officers

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2019

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GENERAL INTRODUCTION

UNIVERSITY STANDARDS

Northern Caribbean University operates in harmony with the beliefs, practices and educational philosophy of the Seventh-day Adventist Church. As such, it encourages students to relate their academic pursuits to their understanding of the Christian faith. Emphasis is placed on the development of sound Christian character while maintaining an atmosphere which fosters in student's commitment and growth in a personal relationship with Jesus Christ. Faith and learning combine to prepare students for a life of practical and useful Christian service.

Students are expected to avoid all forms of personal conduct that would degrade their spiritual or moral behaviour or that would disrupt their scholastic performance. They are required to abstain from unhealthy practices, such as, the use of drugs, alcoholic beverages, tobacco and improper conduct between sexes; and to respect the property of the institution and the rights of others. It is anticipated that students will find the University's environment academically engaging, spiritually inspiring, physically satisfying and personally uplifting. Students who find it difficult or impossible to comply with these standards may wish to seek study opportunities elsewhere.

Applicants who refuse to pledge compliance with these standards will not be accepted at Northern Caribbean University. Students who later find themselves out of harmony with these standards or whose conduct or attitude shows evidence of negative or unco-operative behaviour should expect dismissal.

PHILOSOPHY

The University adopts the philosophy that "True Education means more than the pursual of a certain course of study. It means more than a preparation for the life that now is. It has to do with the whole being and with the whole period of existence... It is the harmonious development of the physical, the mental, and the spiritual powers. It prepares the student for service in this world and for the higher joy of wider service in the world to come." (White, *Education*, p. 13*)*

MISSION STATEMENT

The mission of Northern Caribbean University, a Seventh-day Adventist institution, is to improve the human condition by providing quality, Christ-centered education, achieved through academic excellence, values-based focus, spiritual and physical development, social interaction, and a strong work ethic, thereby equipping each student for committed professional service to all people, and to God.

VISION STATEMENT

Northern Caribbean University will be the premier institution of higher learning in the Northern Caribbean region with a commitment to offering quality and accessible Christ-centered education.

VALUE STATEMENT

Ubi Semper Discimus – Where learning never ends

CORE VALUES

Affirmation

Christ-centeredness
Collaboration
Diversity
Excellence
Innovation
Integrity
Leadership
Respect
Responsibility
Service

HISTORY

Northern Caribbean University (NCU) is a Seventh-day Adventist English-speaking University. It is located on a two hundred-acre property two miles south of the town of Mandeville, in Manchester, Jamaica. It is jointly owned and operated by the Jamaica Union Conference of Seventh-day Adventists which has its headquarters in Mandeville and the Atlantic Caribbean Union Mission which has its headquarters in the Bahamas. The University is a private co-educational, liberal-arts institution, offering a number of professional, pre-professional and vocational programmes and is the only multi-disciplinary tertiary institution serving rural Jamaica. Its enrolment exceeds 5,000 students from over 35 countries.

Founded in 1907, NCU is the oldest private tertiary institution in Jamaica. The institution began by offering courses up to the twelfth grade. As the offerings developed to include theology, teaching, business and the natural sciences, it became a junior college. Formerly known as West Indian Training College, the institution achieved senior college status in the

late 1950s when it began to offer the Bachelor's Degree in Theology and was renamed West Indies College. Since then, baccalaureate programmes in over four other disciplines were added. Beginning in 1974, the College served as an extension site for Andrews University, Berrien Springs, Michigan (USA), offering graduate programmes in Education, and Religion and Theology. In 1999, the College was granted university status by the Jamaican government under the name Northern Caribbean University. Since then, the University began offering graduate programmes in business, counselling psychology, education, religion and the sciences.

CULTURE

The University seeks to establish an academic culture that fosters excellence in the production and utilization of knowledge. Toward this end, graduate work at Northern Caribbean University pays serious attention to local, national and international issues. The Office of Graduate Studies & Research ensures that the graduate programmes focus on the needs of humanity, and that students hold this view as central to their work while they seek to advance their own development. A major goal of the University is to embrace the academic, physical, social and spiritual development of its students and the nation. Graduate courses and programmes seek to transform human and environmental variables in pursuit of a higher quality of life here on earth while preparing for eternal citizenship in the hereafter.

ACCREDITATION

Northern Caribbean University has institutional accreditation from the Adventist Accrediting Association, an international accrediting body of the International Board of Higher Education (IBHE) of the General Conference of Seventh-day Adventists, which is headquartered in Maryland, USA. The institution is authorized by the University Council of Jamaica as an approved centre for the granting of degrees. Each programme has been awarded accreditation by an accrediting agency.

The University is recognized by the Students' Loan Bureau in Jamaica, the United States Department of Education, the Canada Student Loans Programme and the Alberta Student Assistance Programme, as an approved centre of higher education for the purpose of loans and grants.

AFFILIATIONS

Northern Caribbean University (NCU) has affiliation agreements with Andrews University in Michigan, Loma Linda University and La Sierra University in California, The University of the Southern Caribbean in Trinidad and Tobago, Oakwood University in Alabama, Babcock University in Nigeria, the University of Wisconsin at Whitewater and the University of Maryland – Eastern Shore. NCU is a member of the Research and Development Consortium that brings together the University of the West Indies, University of Technology, Northern Caribbean University, Scientific Research Council and other related agencies and institutions. NCU also plays an integral role in the University Diabetes

Outreach project (UDOP) which sponsors a yearly medical conference that seeks to educate medical practitioners and the public in respect to the prevention, control and management of diabetes mellitus and its complications. In addition, NCU collaborates with the Bureau of Standards Jamaica to provide training and services.

MEMBERSHIPS

Northern Caribbean University is a member of the Joint Committee for Tertiary Education (JCTE), the Association of Caribbean Tertiary Institutions (ACTI), the University Council of Jamaica (UCJ), the Joint Board of Teacher Education (JBTE), and the Caribbean Area Network for Quality Assurance in Teacher Education (CANQATE). The School of Religion and Theology is a member of the Inter-American Adventist Theological Seminary (IATS) which is headquartered in Miami, Florida (USA).

SCHOLARSHIPS

The University, especially through its Office of Graduate Studies & Research and in collaboration with the Office of Scholarships, seeks to keep graduate students apprised of scholarships which might be available for graduate work, nationally, regionally and internationally.

ALUMNI RELATIONS

The Office of Alumni Relations is dedicated to supporting Northern Caribbean University through programmes and activities designed, developed and implemented to create and enhance lasting and mutually beneficial relationships between the University and its alumni.

The Office of Alumni Relations:

- Shares news and information about NCU and alumni work/activities.
- Gives awards to community members or groups for outstanding work.
- Makes presentations to community groups, churches, schools, citizens associations and business organizations.
- Hosts cultural and religious programmes which reflect the ideals of the University.
- Establishes and maintains a rich relationship with alumni and alumni chapters – nationally, regionally and internationally.

LECTURE SERIES

The University believes that a lecture series conducted annually will serve to motivate students in their quest for excellence. To fulfil this goal, the following lecture series were established:

HAROLD M. JOHNSTON LECTURE SERIES

This lecture series was introduced in 1983 to honour the memory of a distinguished Jamaican scholar and alumnus of Northern Caribbean University. Sponsored by the College of Humanities, Behavioural and Social Sciences, the series provides opportunity for scholars, local, regional and international, to make presentations on a variety of current issues and topics.

K. G. VAZ LECTURE SERIES

Inaugurated by the School of Religion and Theology in 1998, this lecture series honours an outstanding scholar and renowned theologian, Kenneth G. Vaz, who gave distinguished service to Northern Caribbean University in the Department of Religion, as it was then, and as President of the then West Indies College. This annual event brings to the campus, scholars who provide an academic perspective on theological and related issues.

W. D. CARTER LECTURE SERIES

This lecture series is named in honour of W. D. Carter who established the W.D. Carter Library of Caribbean Economic Development in 1999, housed in the H.S. Walters Resource Centre. The lecture series so named is in commemoration of Carter's lifetime achievements in real estate, health care and entrepreneurship. The lecture series is held once per month and conducted jointly between the College of Business and Hospitality Management and the W. D. Carter Centre. It is open to the NCU family but in particular, for the students of the College of Business and Hospitality Management, given its primary focus on business and economic matters.

CONFERENCES, CONVENTIONS AND SYMPOSIA

The University promotes and stages major events that provide exposure to the university and stimulate academic excellence among its faculty, students and community, both local and international.

The International Literacy Conference

This is a biennial conference devoted to the advancement of reading as the foundation for all learning which brings to the campus local and international presenters and participants under the auspices of the Department of Teacher Education in the College of Education and Leadership.

The IRAE Convention

This is a biennial event that brings together local and international inventors, researchers and Entrepreneurs in a convention and trade show staged on the University campus. Its purpose is to stimulate research, inventions and trading among the people of the region.

The Science Symposium (Research Week)

This is an annual event staged by the Department of Biology, Chemistry and Environmental Sciences within the College of Natural and Applied Sciences, Allied Health and Nursing during the Research Week. This event seeks to promote research, discoveries and general advancement in science.

The Current Trends & Issues Conference (Research Week)

This is an annual conference hosted by the College of Business and Hospitality Management. It focuses on business trends and issues in the nation, the Caribbean region and the global environment. The target audience consists of senior undergraduates and graduate students. Its intent is to equip graduands of the College with a leadership mind set, and provide currency and relevance on trends and issues with which they have to deal in the marketplace.

SRT Theological Symposium

This annual Theological Symposium is held in the month of November and caters to the theological development of registered students in the School of Religion and Theology and the wider community of ministers of religion, support groups and local church leaders. In this initiative, scholars of international bearing are invited to share their expertise in those areas of discipline after which there is deliberate responses from the audience. Attendees earn Continuing Education Units for both presence and participation.

Purpose of the Manual

The Office of Research and Grants is the primary agent of the University's current thrust to foster research. It monitors all matters affecting the integrity of research and the impact of statutory regulations and policies. Its activities, projections, emerging role and functions within the recently chartered NCU-1999 are herein described. Like its host, it is undergoing change as it facilitates, informs and directs the emerging research agenda and culture of this University.

Research activity may be an individual initiative or a collaborative effort with local, regional or international collaborators.

The Authority of the Manual

The policies and procedures in this manual have been approved by the Academic Board and the Cabinet of Northern Caribbean University. They constitute the official policy that governs the conduct of research at this University. The manual is designed to be consistent with general university policy affecting employment, retention and dismissal of faculty as set forth in the Northern Caribbean University Working Policy Handbook.

The policies and procedures became effective June 1, 2004 and were updated in 2014 and more recently in 2018.

The Research Director works in collaboration with the Research Advisory Board and the Institutional Review Board in determining the need, priority, and scientific feasibility of the projects proposed, for which these guidelines have been developed. When adhered to, the procedures outlined will ensure that research proposals are scientifically sound, relevant to society's needs, and not duplicative of effort undertaken elsewhere.

The Goal of the Research Programme

The goal of the NCU research programmme is to create opportunity for faculty to seek solution to current and emerging social and economic issues of local, regional or international importance. This will be done through diligent and timely scientific investigation, using the following objectives:

- To enable faculty to investigate phenomena consistent with the mission of the University and for advancement within their disciplinary areas of competence.

- To provide experiential learning opportunities for graduate and undergraduate students.

- To facilitate the pursuit of knowledge to meet the goals of the wider society.

RESEARCH AND GRANTS GENERAL PROCEEDURES

The Functions of the Office of Research and Grants

Three major functions of the Office of Research and Grants have surfaced since its inception in January 2002. They are reflected by the terms assurance, consultation and compliance.

- **Assurance:** The Office of Research and Grants is involved in the preparation and evaluation of research proposals. It will supervise and monitor protocol. It will ensure that research activities are done in an exemplary manner, in harmony with normative expectations in the major fields or disciplines. This is done through the Institutional Review Board. This board is chaired by the director of the office of research and grants, with members taken from the various colleges of the university.

- **Consultation:** The presence of graduate students on the campus highlights the need for additional training for research advisors. This need has grown with the passage of time. Hence, the Office of Research and Grants assists in advising students and faculty on the design and implementation of research projects, through seminars and workshops on research methods and proposal writing and one-on-one consultation.

- **Compliance:** Research should be conducted in harmony with local and international statutory regulations. The Office of Research and Grants will be expected to provide the necessary guidance in conforming to such regulations through its policies and

procedures. Funding agents also stipulate their requirements for grants in their request for proposals (RFP) which will be disseminated to the NCU faculty.

The Office of Research and Grants has facilitated research activities of visiting students (both graduate and undergraduate), as well as visiting scholars or faculty of other universities. It is conceivable that this function will continue in the future Several Fulbright scholars have conducted research on the campus in during the last few years. It is expected that as other areas become actively engaged in scholarly research, more visiting scholars will seek access to our campus. The Office of Research and Grants will continue to encourage them to do so.

Other functions, such as facilitating the establishment of research programs in academic departments is being pursued so that each department has its full complement of trained research scholars. The objective is to assist departments in conducting research in areas that are compatible with their interests, competence and daily work/activities. To this end, the Office of Research and Grants works with each department to provide support in the design and conduct of research projects and monitor both the implementation of research plan(s) and the preparation of reports.

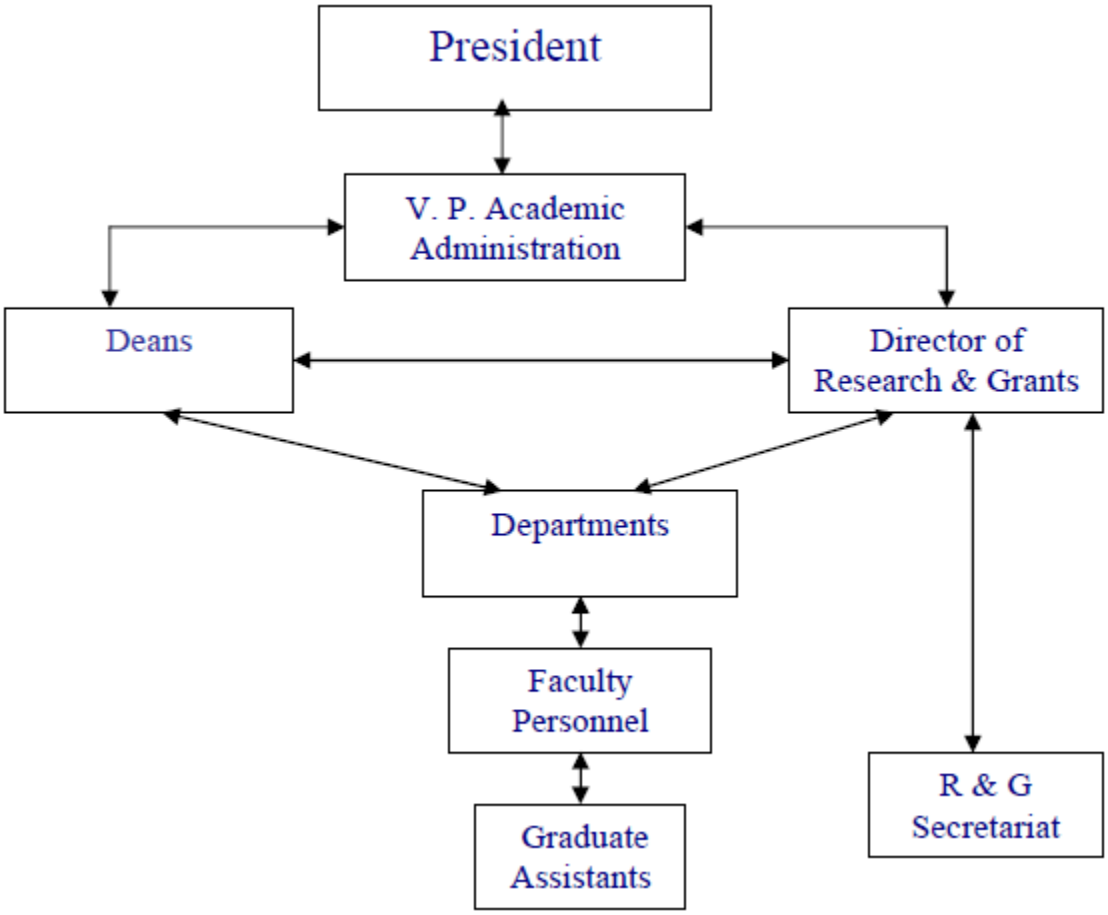
Establishing the Research Programme

The research program is a function of the Office of Academic Administration, and it is administered through the Office of Research & Grants. The Research Director assists the Vice President for Academic Administration with the administrative responsibilities of the program.

Each department head is responsible for the research agenda of his/her department, and may serve as the project coordinator or delegate coordination to a member of faculty. The department head may select faculty members with the appropriate qualifications to serve as principal investigators on departmental projects, or faculty may be given approval for proposals on which he/she is the principal investigator (P.I.) or co-investigator (co-P.I.) of projects being implemented. The Deans of Colleges will have overall responsibility for the research program development and implementation at the College level.

Specific responsibilities of research personnel are given in *appendix 1*.

Organisational Structure of the Office of Research and Grants



The research director will consult with deans and department heads in research project implementation. The latter will be responsible for discipline and supervision.

Research Faculty

The department head will be responsible for identifying and motivating faculty capable of undertaking research. Towards this end, department heads may choose to liaise with the newly established Northern Caribbean University Association of Research Scientists (NCUARS). Its goal is to foster an environment in which faculty can engage in research for the pursuit of knowledge and its relevance to the community, and to advance within their disciplinary areas of competence. The association will provide a rallying point for faculty inclined to engage in research aimed at solving socio-economic problems in Jamaica's industry and agriculture. Such faculty will be classified as "research oriented" while others will be "teaching oriented". This, however, does not exclude any member of faculty from engaging in research. In fact, all faculty in a department could be classified as "research oriented", based on their interests. None should be denied the opportunity. On the other

hand, some faculty may wish to be classified as "teaching oriented" and be engaged only in teaching. These too should not be denied the right of that choice.

Release Time

This is a measure whereby time normally used for instruction is allocated to faculty to do research. Instructional time of 27 credit hours per year will be reduced to allow faculty to pursue their research interests. The amount of release time required will depend on the nature of the problem being investigated. The 3 credit hours per year usually allowed faculty for other required duties and responsibilities could also be used for research**.** Resumption of full teaching load is expected if or when the faculty member is no longer engaged in research. The department chair and the faculty member will determine the proportion of time to be devoted to either research or teaching.

When the "research oriented" faculty is not engaged in research, he/she reverts to the "teaching oriented" category to configure work load requirement. Although a faculty member may be classified as "research oriented", his/her instructional time will not be automatically reduced merely on this assumption.

Extra-mural Funding

This refers to grants received by the University for the purpose of conducting research. The institution deducts a percentage for overheads agreed on by the administration on certain items of expenditure such as salaries and wages. The remainder of the grant is used for operational expenses. Normally, the P.I. on release time will have the equivalent salary paid from the grant, for the University to hire adjunct faculty to maintain the teaching schedule. The institution will give to faculty an incentive award of 5% from grants which are received through their efforts.

Initial Proposal Approval

A faculty member wanting to submit a proposal should first consult with the head of department to determine if the project falls within the scope and objectives of the research program. Within reasonable time, the faculty member should further identify the human and physical resources needed for implementation, and whether or not the project can be successfully completed with the financial and other available resources. An agreement with the department chair should be reached allowing for:

(a) the presentation of a Project Identification Document (P.I.D) by the faculty member;

(b) the approval of the P.I.D by the department chair.

Once the approval is granted, the agreement for involvement can be completed with respect to the amount of time required for developing the proposal and undertaking the study.

The P.I.D must state:

(a) The nature of the intended research
(b) The scope of the research
(c) The major purpose of the investigation
(d) The major benefits to be derived
(e) The major resources required to conduct the study
(f) The level of funding projected
(g) The time allocation projected
(h) The period of absence from the main campus (if any)

The P.I.D should be presented and approved at least in the semester prior to the one in which the time allocation can be granted to start the research. If the P.I.D is not approved in the one semester, the faculty member will have to teach in the semester or summer session that follows, while he/she revises that P.I.D or prepares another. Time cannot be allocated for the preparation of a P.I.D. The department chair must receive research requests (submission of P.I.Ds) well in advance of planning for the ensuing semester or summer session. Faculty members who do not submit P.I.Ds on time will be automatically scheduled for teaching.

The decision on the approval/rejection of a P.I.D should be within 2 weeks of submission. This will allow enough time for department chair or faculty member to schedule a research activity or teaching for the ensuing semester/summer session. A P.I.D can be individual or joint, which would follow through for the proposal and actual research. Once the P.I.D is approved, the faculty should commence the preparation of the proposal for approval before the actual research is initiated. The completed proposal should be sent by the department head to the Institutional Review Board along with the completion of the relevant IRB forms, for review and final approval.

DEVELOPMENT AND IMPLEMENTATION OF A PROJECT

Funding

It is traditional for university faculty with interest in research to seek extra-mural funding, which facilitates the development of linkages to government, industry, local and international organizations, and other tertiary institutions. Since very few, if any, institutions of higher learning are usually financially self-sufficient to the point of being able to exclude extra-mural funding, writing research proposals has become a way of life for university faculty worldwide.

Note however, that many funding agencies have their own format for developing a proposal and usually require its use by fund raisers.

In developing a proposal for internal or extra-mural funding, the following should be kept in mind:

a) Resources and infrastructure available for the investigation: these would include laboratory space, equipment, green house, and or field plot; transportation, communications medium and technical or other help available, such as graduate assistants, part-time or full-time research assistants, and casual labour. It is recommended that the principal investigator meets with the head of department (the coordinator) and discusses with him/her these aspects of project implementation.

b) Time required for completing the study may involve release time.

c) The extent of collaboration needed internally or externally for the project to be viable.

d) Accountability concerning the expenditure of grant funds and proper use of equipment and facilities.

e) The research design should be compatible with the research question(s) or hypotheses. Also experts in the field of study should agree that the proposed design is adequate and that its faithful execution will furnish valid and reliable findings. Reviewers will not assume that the research design is valid or feasible. It is the responsibility of the investigators to (i) establish the credibility of the design, (ii) convince the reviewers through logical and persuasive arguments, as well as careful documentation which exhibit a combination of procedural skills and the requisite declarative knowledge that are currently used by the luminaries of the field of study.

f) Although each field of study has its own way of establishing truth, the following is recommended as a general outline of issues that should be addressed in each proposal. It is a general guide; therefore, the specific requirements of each discipline, as outlined elsewhere should be used in the preparation of the proposal.

Nonetheless, it is expected that each research proposal will contain the following elements or characteristics:

1. Problem is clearly stated.
2. Hypotheses or questions are clearly stated.
3. Problem is significant.
4. Assumptions are clearly stated.
5. Limitations of study are stated.
6. Important terms are defined.
7. Relationship of the problem to research is made clear.
8. Research design is described fully.
9. Research design is appropriate for the solution of the problem.
10. Research design is free of specific weaknesses.
11. Population and sample are described.
12. Method of sampling is appropriate.
13. Data-gathering methods or procedures are described.
14. Data-gathering methods or procedures are appropriate to the solution of the problem.
15. Data-gathering methods or procedures are utilized correctly.
16. Validity and reliability of the evidence gathered and that of the data collection instruments or procedures are established.
17. Appropriate methods are selected to analyze the data.
18. Assumptions associated with each data analysis procedures are stated.
19. Assumptions of the data analysis procedure are reasonably satisfied.
20. An Abstract of less than 120 words in which I to 19 are presented.

Additionally, each research proposal should contain a feasible timetable and a reasonable estimate of the cost of the project. Both the cost estimates and the timetable should be placed in the Appendix.

Components of a Research Proposal

Once the P.I. comes to a proper understanding with the head of department, he/she should now proceed to develop the proposal in the following order:

Title: The title should succinctly convey to the reviewer what the investigation is about.

Table of Contents: The table of contents should enable the reviewer to follow the sequence of the proposal coherently.

Executive Summary: This is a summary of the nature of the problem, and how it will be resolved, and the benefits and outcome. Depending on the nature of the investigation, it could range from half to a full page, but it is seldom more.

Purpose: The purpose answers the question - why or for what reason is the investigation being undertaken? The working hypothesis is often expressed under this heading. Seldom is it necessary to include more than half a page to explain this aspect of the investigation.

Justification/Impact: Under this caption, the author states plausible reason(s) why the study is necessary. No effort should be spared in stating its relevance to the institution, community (local, regional or international) or target group. In many instances, great emphasis is placed on "justification", such that it is next to methodology in importance.

Introduction: Previous Work and Present Outlook: The introduction should provide the reviewer with a history of the subject as it impacts the current investigation. This is similar in form to "literature review", the term quite often used alternatively with "introduction". Sometimes the introduction may include unsubstantiated or unidentifiable material, the author of which may be referred to as "Anonymous".

Methodology: This is doubtless the most important and scrutinized section of the proposal. It usually reflects the author's skill, experience, knowledge and mastery of the subject. It could mean the difference between success and failure of the project, even with funding. Usually, the services of a statistician are sought to ensure that data collected are analyzable to provide the information required.

Probable Duration: The author should estimate the maximum period required for the completion of a project. Normally the average life of a project is three years. If changes in objectives or procedures are needed, a new revised project outline should be prepared and submitted by the P.I. Since a project is reviewed annually, continuation of funding depends on making satisfactory progress.

Institutional Units Involved: This refers to the unit in which the research will be undertaken and any other units within NCU that will contribute essential services or facilities. The responsibilities of each unit should be described in detail. Should there be a committee or advisory group in charge of this effort, such information should be included.

Research involving human, vertebrate animals or any hazardous or pathogenic material must receive approval from the institutional review board.

Cooperation/ Collaboration: Currently, cooperation and/or collaboration with units, agencies, organizations and other tertiary institutions outside the University and abroad for effective research is desirable and encouraged. In the wider sense of global higher education, a project could be regional or international, in which case stations, institutions or agencies would be expected to cooperate formally or informally on it. A statement indicating the organizations/agencies and or individuals with which the P.I. proposes to collaborate, and the contribution of each to the project, should be included.

Benefits: Under this heading, the author will outline the good that will accrue to the institution, community, region, society or the world from such an undertaking. It is a measure of the advantages to be gained through painstaking and thorough scientific investigation.

Outcomes: The consequences that are derived from an investigation may be beneficial. It adds to the worthiness of a proposal if the outcome(s) have positive long term effects such as generating employment, removing an obvious health hazard, and enhancing an educational programme that will benefit a targeted group of individuals.

Budget: The budget discloses the kinds of goods and services on which money will be spent, with a cost estimate attached. In their second edition of ***Proposal Writing***, **Coley and Scheinberg (1999)** identify three types of budgets – **line item, performance or functional and program budgets.** "Line item" appears to be the simplest and most frequently used. To each line item is attached a cost which when totalled, represents the budget for the project. It is usual to follow the budget with "Budget Notes", which explain in more detail how a line item cost is derived. Line items frequently making up the budget are Personnel, Supplies and Material, Communications, Equipment, Publications and Overheads.

Resumes: Scientists who are directly or indirectly involved in the project should include a resume which normally follows the budget. Information in the resume generally includes achievements in the investigator's area of competence. This provides for the funding agency an index of the quality and the degree of exposure the individual has acquired in the subject over time. A resume of one, or at most two pages is usually adequate.

Use of an Appendix: At times it becomes necessary to include invoices and other documentary evidence for clarification regarding headings such as justification, methodology and costs, which cannot be conveniently placed in the text. The creation of an appendix at the end of the proposal is to accommodate this type of information.

Peer Review: Before submitting a proposal for funding, it should be reviewed by a committee consisting of the department head, two members of faculty from the department, and two persons from outside the department knowledgeable or familiar with the area of research. A reviewer must provide written appraisal and comments which may be used for improving the proposal. A review form will be provided for this purpose.

The P.I. must respond to all substantive comments and must give reason for excluding any such comments.

The department head will review the revised proposal which he/she will submit to the research director along with a list of the reviewers and their comments. A checklist for use by the department head is available.

The research director will determine if additional review and substantive revision is necessary. The proposal is then sent to the IRB, for review and final approval.

If approval is granted by the IRB, the research director, will scrutinized the proposal for budgetary correctness and it is then transmitted to the funding agency.

The Award: Following notification of an award, the P.I. will normally respond to the grantor within a reasonable time (15-30 days), accepting the terms of the award, and proceed to implement the project as planned. In certain instances, the scope of work for the project may have to be revised because funds are not sufficient to meet the original objectives.

Project Implementation

Funding: Once funding has been received, the principal investigator together with the team will proceed to make arrangements for implementation as proposed.

A number of preparatory activities will be put in place in order to get the program underway, and to ensure that the outcomes of the study are achieved. Some of these are purchase of equipment, site preparation and staffing, formal and informal agreements within and between departments, collaborative agreements with off campus institutions and organizations, information dissemination and evaluation mechanisms. The form these activities take will vary with the kind of proposal being implemented. In principle however, the P.I. should ensure the preparations in place are adequate to begin the investigation. If it is envisaged that a change in implementation strategy may be necessary at some point in the study, then advance planning should be made for it.

If the financing of the project is by way of reimbursements, the Research Director should bring this to the attention of the University's accounting system and the details worked out before implementation begins. Normally, the P.I. is required to request the purchase of an item on an appropriate form which gives details of the purchase, including name and address of vendor, price with possible discounts, and a complete description of the article. Whereas a purchase request (PR) is made by the P.I., a purchase order (PO) is usually issued by the University containing much the same information as the PR, but with the addition of delivery time and possibly, mode of transport.

Where a project is being implemented by more than one individual, it is usual to identify a leader who is called the P.I., and the others Co-P.I.'s or Co-Investigators.

The Time Line: As far as possible, every effort should be made to adhere to the time line for completion of the project. This becomes important especially when adjunct faculty has to be hired to replace the P.I. in the classroom. Keeping on track is also important with respect to the funding mechanism. As a rule, funding agencies prefer new projects rather than extensions, except in extenuating circumstances such as national disasters, war, or other upheavals**.** Also, to be able to complete a project on time with outcomes as proposed, speaks well of the management ability of those involved in its implementation, as well as individuals responsible for scientific and technological inputs.

Purchases: *Equipment, goods and services, supplies, miscellaneous expenditures*: The proposal will normally include the cost of equipment, goods, and services, expendable supplies among others, to be purchased for the study. For items costing in excess of $5000.00, the P.I. should consult with the project coordinator/department head and Research

Director before requesting purchase. Payroll documents, purchase requests and other procurement documents should first be signed by the P.I., then by the project coordinator/department head prior to submission to the Office of Research and Grants, from which they will be sent to the VP for Academic Administration for approval. From the VP's office they will be forwarded to Finance and Industries for further processing.

Upon receipt of the goods, the P.I. will then route invoice and receipts back through the Office of Research and Grants. Any price change or other charges should first be approved by the project coordinator/department head, followed by the Office of Research and Grants.

Travel: When travel is undertaken, the rules of the University, outlined in Chapter 3 of the NCU Working Policy Handbook, should be applied.

Budget Revision: Budget revisions, which should be kept to a minimum, will be approved as necessary by the coordinator/department head, the Office of Research and Grants, and the Dean where applicable.

Replacement of P.I.: If a P.I. resigns from the faculty or has to be replaced for other reasons, the coordinator/department head and the Research Director will decide on whether or not a replacement should be made, and accordingly forward a recommendation to the Dean, who will consult with the Vice President for Academic Administration on the matter. A complete inventory of project equipment and supplies should be undertaken prior to the termination of the individual's employment.

Purchase of Motor Vehicles: If it is planned to purchase a motor vehicle with funds from an approved budget, the Director of Purchasing should be contacted. He or she will guide the P.I. and project coordinator/department head in the process. As usual, the purchase request should be routed through the Office of Research and Grants.

Hiring of Personnel: The P.I. in consultation with the coordinator/department head, will identify the need for project personnel (professional, technical and/or supporting staff), after which the Office of Research and Grants will be contacted with a request to fill the vacancy and to verify that there is funding for the position. The Human Resource Department will then be requested to recruit for the position. The Vice President for Academic Administration will approve the hiring of the successful applicant. To complete the hiring process, payroll documents will be prepared by Finance and Industries, detailing the conditions of employment. This is normally preceded by a letter from the President offering the position to the successful candidate. Copies of these documents will be made available to the Office of Research and Grants for its records.

Employment Termination: If for any reason employment is terminated, the individual should follow the guidelines as set forth in Chapter 5 of the Northern Caribbean University Working Policy Handbook.

Grievance: The individual should follow the guidelines outlined in Chapter 1 of the Northern Caribbean University Working Policy Handbook.

Discipline: Northern Caribbean University has provided clear, fair and useful measures for maintaining and improving work ethics on its campuses. There is also a procedure in place to help management in dealing with unacceptable personal conduct. For detailed information, please refer to the 2004 Northern Caribbean University Working Policy Handbook.

Project Monitoring: The department head coordinates project implementation and monitors its administration according to the plan proposed in the original proposal. Should it be necessary to make significant modification which could be a change in, or a new objective, changes in personnel or budget allocation, it should be approved by the project coordinator and communicated to the Dean and the Office of Research and Grants. Together, the coordinator/department head and the P.I. should submit an annual report to the Office of Research and Grants.

Extension: The Research Director in consultation with the Dean and coordinator has the authority to redirect, extend or terminate a project regardless of funding source when the evidence suggests that satisfactory progress is not being made. If extension of a project beyond the termination date is being sought, an application accompanied by an up-to-date progress report and a justification for the extension, including anticipated expenditure prepared by the principal investigator, should reach the Office of Research & Grants sixty (60) days prior to the termination date. The Research Director approves and forwards the application to the funding agency or the appropriate section of the University.

Project Evaluation: A report on the progress of the project should be submitted to the Office of Research & Grants within six (6) months after the date of the approval letter from the Institutional Review Board. This report should include the extent of data collection and analysis and challenges encountered during the study.
On-going research projects will be evaluated annually to determine the achievement of goals and objectives. A good time for this exercise is usually at the end of the academic year. The evaluation will determine if the project is being implemented, administered or operated within the framework proposed in the original document. Also included are reported achievements and impacts, as well as barriers to successful completion. The real purpose of the evaluation should be a strengthening of the research program and creating opportunity for professional growth and development. The evaluation process should highlight: Progress on stated objectives

- Conclusions if any (or preliminary results from ongoing studies)
- Information dissemination and impact of project activities, findings/ outcomes.
- Collaborators (if any) and their impact on the success and/ or failure of the study.
- Impact of the study on students experiential learning and mentoring.
- Achievements of the study with regards to capacity building in the department, school, college or the university.
- The global perspective: what contributions or impact has the study made on widening one's horizon on globalization in the area of higher education?

During project implementation, peer review and evaluation will be acceptable. However, at termination, it would be more desirable to include on the evaluation team, professionals from without the University.

Project Reporting

It is the responsibility of the P.I. to keep the head of department informed on the progress of the investigation. This may be accomplished by bilateral discussions from time to time, or through written reports submitted upon request. The funding agency usually requires progress reports for which the P.I. is also responsible. When requested, financial reports are supplied by the University.

The following format is to be adopted for reporting the progress of projects to the Office of Research and Grants. All projects should present a yearly report or a copy of a final publication in the event the project is completed. In the event that the project is completed and a final publication was not done, a final report is being requested.

Introduction: In a few sentences, introduce the report and the project, and briefly state the status of the project. The heading "Introduction" or "Summary" may be used or this can simply be an opening paragraph.

Background: This should be a brief review the project. Major tasks that should have been completed should be highlighted. These will be addressed further in the following section.

Accomplishments: A Summary of what you have done in the time frame covered by the report should be the main focus of this area. Major tasks completed and significant findings or results should be stated. Only address findings that in your opinion are relevant to the report and that is the reader (audience) needs to know. One should not waste time providing information that is not relevant to the goals of the reader. Bulleted lists are a good format to use in this section as it easily summarizes the work. Subdivisions can be introduced in this section to make it easier for the reader (audience) to quickly garner the information contained within.

Problems: All major problems encountered should be addressed in this section. An explanation of the problems, as well as an explanation of how the problems were solved or how these problems will be addressed/solved should be included. If changes to the project are necessary based on the problems encountered, these should be adequately stated and addressed. Bulleted formats are also a good format to include here.

Future Work: Work remaining on the project should be outlined; this should include completion dates and estimates of time. Changes made to the project plan and any other changes that have implications for future work should be noted here.

Conclusion: The conclusion in longer projects needs to again summarize the overall project status; for shorter reports, this summary can be a single sentence. If immediate actions are needed from the reader (audience) such as more money, approvals, meeting

requests, or other, these should be clearly stated here. An offer should be extended to answer additional questions or request feedback from the reader (audience) here.

Authorship and Publications

Publications

It is traditional and very desirable that the results of a study be published in a refereed journal or other type of publication accessible to workers in that discipline. The P.I. may publish his/her work either singly or collaboratively; it is a matter usually left to his/her discretion. However, current trends suggest that professionals involved in a study should be mentioned as co-authors unless they prefer to be excluded.

When an article is submitted for publication, it usually undergoes critical review by professionals selected by the journal or periodical. It often happens that the author is requested to make certain amendments ranging from the use of English to syntax. It is usually best for the author to respond promptly to these requests which will help in shortening the time between submission and publication.

The format for a publication is in many ways similar to that for writing a proposal. There should be a title, followed by the name of the author(s), table of content, executive summary or abstract, an introduction, experimental procedure, or more often, materials and methods, results and discussion, and literature cited. An appendix may also be included if necessary.

Measures to take when authoring a publication: Data obtained from well-designed experiments usually present little or no problem in analysing. It means, however, that initially the P.I. must take the necessary steps to ensure that the experimental design is appropriate.

1. The P.I. should ensure that the data is analysable, reflecting the results from the study.

2. The P.I. should consult with a statistician and other experienced professionals as necessary.

3. He/she should become familiar with the rules of the publisher and be prepared to abide by them.

4. The P.I. should provide the coordinator with a copy of the paper to be published, the journal or text in which it will be published, and the approximate time it will be available to the public.

5. The P.I. will follow the conventional way in reporting the study -Title, Abstract, Introduction, Justification, Objectives, Materials, Methods, Results and Conclusion, Benefits, Outcomes, Literature cited - and in completing the literature reviewed e.g. Brown, John W. and H. Williams. 2004, "The effect on protein content in corn (*Zea mays*) exposed to gamma radiation". *Trop.Agr*. vol. 15# 3, 147-155

6. The P.I. should respond promptly to the publisher's request (if any) to make modification to the text, since it will usually shorten the time between submitting and actual publication of an article.

7. Once published, the P.I. should deposit a copy of the paper in the University Library and the Office of Research and Grants.

Authorship

Authorship is important in academic life and can influence credibility, promotion and tenure. It implies accountability and responsibility for the material in an article. In addition, authors can be sued for libel. These factors imply that authorship should be taken very seriously.

There is no universally accepted standard for assigning authorship. The principles, customs and practices governing authorship differ significantly from one discipline to another and researchers should be aware of the practices within their own disciplines and abide by the stipulated journal requirements (adapted in part from the University of Cambridge, UK) (https://www.research-integrity.admin.cam.ac.uk/research-integrity/guidelines/guidelines-authorship).
This document outlines NCU's guidelines and the following criteria for authorship is aligned with those established by the International Committee of Medical Journal Editors (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

An individual qualifies as an author if she/he makes a substantial creative contribution in one or more of the following phases of Research.

1. Conception and design of the study

2. Implementation of the study design or acquisition of the data. This means that the individual conducting the experiments or carrying out the study should be operating at a higher cognitive level than mere routine tests or routine administration of a survey instrument.

3. Involvement in data analysis. Running the data through a statistical programme is not sufficient to be considered an author. However, finding a novel way to analyze the data or interpret the data and data analysis which is time consuming and labour intensive constitutes substantial contribution.

4. Writing the paper. This involves writing the first draft and /or making substantial revisions to the paper for important intellectual content and approval of the final draft for publication

Persons who do not meet at least two of the above-stated criteria should not be listed as authors. All individuals who meet the first criteria should have the opportunity to participate in the other aspects of the study (#s 2, 3, 4). The contributions of other persons could however be acknowledged in the paper. For example, those who may proof-read the paper or provided administrative support for the project.

Collaborators should determine beforehand who is responsible for a particular aspect of the study (inclusive of writing the first draft) and the order of authorship on a given publication. The addition of new researchers during the course of the study should be agreed upon by all researchers/co-authors.

Student Authorship

A student who has worked on a research project for the purposes of a thesis or dissertation should be provided the opportunity to publish his/her work in peer-reviewed journals within the appropriate discipline. The student, having done the majority of the research and written the paper has the right and privilege to be first author on the article. Other authors should include the student's advisor/supervisor, who has been involved in the project and would have contributed to the intellectual content of the study.

The faculty advisor/supervisor, being the expert or senior author should be the corresponding author in publications emanating from a student's dissertation in which the student is the first author. The Graduate student and his/her faculty advisor have the right to determine who the other authors should be based on the above-stated criteria for authorship. A student who feels that he/she is being asked to provide authorship to any individual who does not meet the above-stated criteria for authorship should seek guidance and support from the Head of Department (HOD). If the HOD is unable to assist, the student should consult with persons higher up in Administration, namely the Dean of the College/School and/or the Academic Vice-President.

Intellectual Property and Copyright

Intellectual Property (See Intellectual Property Policy document of Northern Caribbean University)

It is conceivable that research sponsored or otherwise carried out at Northern Caribbean University may result in an invention -physical or methodological- to which the investigator or institution would like to have a monopoly or exclusive rights for a specified time as allowed under the law. If or when this occurs, the P.I. should, through the University's administration, apply for a patent, a license or commercial handling of the material as applicable. Until the University develops policies and procedures for dealing with

intellectual property, it is advisable that the regulations issued by the Jamaica Intellectual Property Office at 1B Holborn Road, Kingston 10, be followed.

Copyright (See Intellectual Property Policy Document of Northern Caribbean University)

Probably, the most important consideration under this heading is helping to identify and address educational needs of the faculty and others related to compliance with copyright policies and guidelines, and the resolution of disputes involving copyright ownership.

In time, Northern Caribbean University will have in place such policies and guidelines to which faculty will have access.

NCU INSTITUTIONAL REVIEW BOARD

Terms of Reference

Preamble: The NCU Institutional Review Board (NCUIRB) is an ethical review body designated by the administrators of the University to review, approve, and monitor, biomedical and behavioural science research involving human participants. Additionally, all research projects designed to be conducted on or off the campus of Northern Caribbean University by or involving NCU personnel (undergraduate and graduate students, staff, and faculty) should be approved by the NCUIRB prior to the commencement of the research. The number one priority of the NCUIRB is to protect human subjects from physical or psychological harm and provide critical oversight for this research. The NCUIRB also ensures that vertebrate animals used in research are treated in an ethical manner and that research involving hazardous materials and chemicals follow industry approved safety procedures and guidelines before, during and after research execution.

It is the responsibility of the NCUIRB to protect participants of any study and simultaneously protect the University from any harm including damage to image and or reputation, and any legal, financial or other type of liability that could result from the misuse or abuse of the research granting privileges extended by the board. All research projects MUST be reviewed by the NCUIRB for conformity to institutional, national, and international standards, or approved for exemption from this process as the case may be. All researchers with ongoing projects who are not in possession of a document providing a waiver or an approval from the NCUIRB should submit an abstract so that a determination can be made for a waiver or for further documentation for full review.

Membership and appointment: The NCUIRB is made up of all the deans of the colleges or their designee, as well as the senior managers from the Office of Graduate Studies and Research. Additionally, select members of faculty are invited to be members of the board. Members are appointed by the office of graduate studies and research at the recommendation of the deans and the chair of the NCUIRB. Membership on the NCUIRB is for duration of one (1) year and is automatically renewed unless revoked by the deans, office of graduate studies and research, or the chair of the NCUIRB.

Chairing: The chair of the NCUIRB will be the Director of Research. In the absence of a Director of Research, The Associate Vice-President (AVP) for the Office of Graduate Studies and Research (OGSR) will assume that responsibility. In the event that there is no AVP for OGSR, the Vice-President for Academic Administration will appoint a dean to act as an interim chair.

Frequency of meetings: The NCUIRB will purpose to meet on the fourth Wednesday of each month, however, in the event this does not occur, meeting must be held at least every three (3) months at the least. Documents to be reviewed will be made available to the committee members three to five days before the meeting date. Submissions to the NCUIRB should come in from applicants by the 15th of each month. At least two

reviews are required per submission and the committee reviews the report from each reviewer and makes recommendations by vote to the chair of the NCUIRB.

Record of meetings: Meetings will be recorded by the administrative assistant in the office of research and grants or by an assigned recorder.

Reporting mechanism: The NCU IRB reports to the Office of the Vice-President for Academic Administration. Reports from the NCU IRB will be included in the quarterly written report of the Director of Research.

Functions: The NCUIRB has the primary responsibility to guide the policies and procedures of the Office of Research and Grants that relate specifically to the ethical and environmental considerations that govern all research projects being conducted by faculty, doctoral students, masters' students, and by others outside of the institution wishing to conduct research on NCU campuses. Decisions made by the board on research projects, policies and procedures that govern the functioning of the NCUIRB are final, except where there is the need for permission to be taken by a higher university body. Recommendations can be sent for ratification to the Academic Council, the Administrative Council, and or the Cabinet.

Payment of Fees for the Review of IRB documents from Non-NCU source

Periodically, the NCU IRB receives applications from students/faculty of Universities overseas and from other institutions in Jamaica. An administrative fee of three thousand five hundred dollars was voted to be charged for non-NCU research applications.

IRB Minutes

Minutes of each IRB are recorded in writing by the Dissertation Secretary who is the Administrative Assistant assigned to the IRB. The IRB Chair will review, periodically, each set of minutes to evaluate the accuracy of determinations and subsequent justifications. Minutes are distributed to all IRB members (chair, members, and alternates), prior to an imminent IRB meeting. A vote for approval of those minutes takes place at the convened meeting. The approval of the minutes is documented in the minutes of the IRB meeting. IRB minutes may not be altered once approved by the IRB unless the IRB requests the revision and votes on approval of the revised minutes. A copy of the minutes is provided to the Academic Board. This informs the Academic Board of all actions taken by the IRB.

Minutes include:

1. Overall attendance at the meeting, including all members present for any aspect of the meeting. The minutes will document when an alternate member replaces a primary member.

2. A list of all studies brought to the Board with the respective information:

a. Actions taken and decisions made by the Committee:

    i. Approved

    ii. Conditional approval, pending required modifications

    iii. Deferred

    iv. Disapproved

b. Votes will record the number of members voting for, against, and abstaining, and the names of IRB members listed under "Members Present" who were absent from the vote. If a member was absent due to a conflicting interest, it is documented in the minutes and indicates the member was absent from the room for the discussion and vote.

c. The basis for requiring modifications to the research proposal or consent documents or for disapproving the research proposals;

d. A summary of the discussion of controversial issues and their resolution;

e. A summary of discussion of issues pertinent to the protocol,

f. Minutes will also document, by referencing the reviewer form, determinations required by the regulations. These determinations include those for waiver or alteration of consent, waiver of consent documentation, and research involving vulnerable groups.

3. A list of all actions such as expedited reviews and exempt determinations that were taken during the previous month outside of the IRB meetings. Minutes will include separate deliberations, actions, and votes for each IRB application undergoing initial or continuing review or amendments by the convened IRB. Vote totals for each action will be recorded in the minutes by listing the total number of votes, along with the breakdown of members voting for, against, and abstaining. The IRB minutes will list all suspended and terminated studies that occurred during the previous month.

IRB Approval Process

The IRB the University committee responsible to ensure the protection of human and animal subjects involved in research conducted at the university or in the name of the university. This committee is also responsible to ensure that research proposal provide for the proper use and disposal of biological and chemical hazardous materials.

The IRB assures minimal risks to subjects and that these minimal risks are reasonable based on expected benefits, and proper research construction. All faculty and graduate students who wish to engage in research must complete the IRB application form and must receive IRB approval before the research is commenced.

The IRB is composed of members taken from each college or discipline within the university. The group meets on the once each month on the fourth Wednesday. Application to be considered at a particular sitting must be received in the office of Research and Grants three weeks before, that is, during the 1st week of the month. Six copies of the application must be submitted to the Office of Research and Grants for distribution to the board members; one electronic copy must be sent to the OR&G (research@ncu.edu.jm) for the archives.

Applicants who wish to have their application expedited must submit three copies for distribution and an electronic copy for the archives. The applications will be assigned a tracking number after which it is reviewed by the chair of the committee and two other members. If approval is granted by the three reviewers; the applicant will be notified in writing and the research may commence. If approval for expedited review is not granted, requests will be made for an additional six copies of the application for the normal review process.

IRB Application Regulations

(i) All undergraduate research being conducted as practice research within the class (not real research) will **not** be reviewed by the IRB.

(ii) All undergraduate research (not practice research or class projects) must be reviewed by the Departmental or College Research Committee before being sent to the IRB.

(iii) All Graduate Research projects must be ***vetted*** by the Department and signed by the Progamme Chair and Dean before it is sent to the IRB. The Dean's signature indicates final approval of the research project, and that the project meets the highest standards of quality in research design and methodology expected of the university and its accrediting bodies.

The vetting process will involve the following:

(a) The student with the guidance of the supervisory committee will determine the scope of the research and complete the initial proposal
(b) The student will be required to defend the proposal in a seminar which includes the supervisory committee and other faculty and graduate students in the department. The Department has the authority to invite other select persons to the proposal defense. Any modifications to the proposal will be made, thereafter.

(c) After successfully defending the proposal, the IRB application will be completed and the relevant sections will be signed by the student, Dissertation Chair and Dean of the faculty prior to submission to the IRB.
(d) The Dissertation Committee should ensure that all the relevant appendices to the completed IRB form are attached. These include but are not limited to the data collection instruments (e.g., Standardised instruments, Surveys, questionnaires, etc.), participant information letters, informed consent forms, permission letters and certificate of ethics training.
(e) Measurement considerations: Standardised instruments must be accompanied with relevant psychometric information (validity and reliability within the population of interest); while developed surveys and questionnaires or open source instruments must be piloted tested and preliminary psychometric data must be included in the proposal.

Expedited Review – (Ten days from receipt of application to complete review).

Research with no risks, or minimal risk to subjects (human over 18 and vertebrate animal) may be granted expedited review. To ensure the process moves quickly, please attach the necessary documents, such as survey instruments, informed consent forms, collaborator's information and investigator declaration form. The applicant will be notified of the decision of the committee in writing with an attached copy of the committee's comments.

All other documents will receive full IRB review and the applicant will be notified in writing of the committee's decisions and recommendations. A copy of the Board's comments will be attached. The IRB response will be sent to the principal investigator and the department head.

Research Protocol for Class Projects Requiring IRB Submission

In the event that students in an undergraduate or graduate class are conducting projects as a requirement for their coursework, a formal IRB submission is not required. Instead, as briefly as possible, prepare your Research Protocol by completing the following and turn that in (electronically through the instructor of the class) to the IRB for expedited review:

1. **Title**: The title should represent what the investigators intend to do. It should be as short as possible but long enough to clearly explain the overall purpose of the project.

2. **List of Investigators (Include school ID#s):** All persons who are involved in the project should be listed here.

3. **Objectives:** The purpose of the study (research questions and / or study objectives) should be clearly and succinctly stated. In experimental designs, objectives may be stated as hypotheses to be tested.

4. **Background and Rationale:** Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. Describe the significance of the research including potential benefits for individual subjects or society at large.

5. **Procedures:** The procedures should include the following:

    a. **Research Design:** The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will be used.

    b. **Sample:** Describe the sampling approach to be used. Identify the procedures that will be used to recruit, screen, and follow study volunteers. Specifically define the study sample (number of subjects to be enrolled, characteristics of subjects to be included in and excluded from the research, and whether this will be a random or convenience sample).

    c. **Measurement/Instrumentation:** Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide information regarding the validity and reliability of selected measures.

    d. **Detailed study procedures:** Methods for collecting data and for avoiding/minimizing subject risks should be included. Include a timeline for subject participation in the project. Identify how subject confidentiality will be safeguarded (plans for coding data and for securing written and electronic subject records). Indicate how long personal information will be stored once the study is completed. Methods will vary with the research approach used (qualitative, quantitative). The selected methods should be sufficiently described to justify the use of the approach for answering the defined research question. Methods should also be described in adequate detail so that IRB members may assess the potential study risks and benefits.

    e. **Internal Validity:** Threats to internal/external validity should be considered. Describe measures that have been taken to avoid study bias.

    f. **Data Analysis:** Specify the analytical techniques to be used by the researcher to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

6. **References:** Include a reference list of literature cited to support the protocol statement.

(Developed by the College of Education and Leadership, Department of Graduate Education and Leadership at Northern Caribbean University; adapted from the Institutional Review Board of the Ohio State University)

Human Subjects Protocol

Research projects that use human subjects must be reviewed and approved by the Institutional Review Board (IRB) before the study begins. The principal investigator**(s)** or the student's advisor should obtain, complete and submit the appropriate IRB forms to the Office of Research & Grants.

The IRB will review each application with a view to (i) safeguarding the rights of and welfare of individuals who participate as research subjects, (ii) protecting the student researcher(s) and the faculty members, (iii*)* ensuring that the interests of Northern Caribbean University are served and (iv) maximizing the potential benefits to the Seventh-day Adventist Church and its agents.

The review of each project will be conducted by using established criteria of each discipline/field. These will include the three main canonized areas in the Belmont Report, and the Nuremberg Code, namely: (a) respect for the persons who participate in the research, (b) beneficence i.e. protection from harm, maximizing benefit, and (c) justice or equitable distribution of benefits and burdens of research. These areas and other concerns will be highlighted and used in the following section

Major Criteria

The above referenced areas of concern, especially the informed consent of research participants, form the basis for the seven elements of the major criteria or standards by which each project will be judged.

Informed Consent

The principle of voluntary and informed consent of the human subject is primary and essential. "Informed" emphasizes the importance of ensuring that each participant made an intelligent decision. This implies that (i) the participant had the capacity to consent, (ii) there was freedom from coercion, and (iii) each research subject comprehended the risks and benefits of the study.

Competent and appropriate individuals should represent individuals who may not be able to make an informed consent. The researcher should therefore inform either the research subject or his, her representative beforehand, of (i) all aspects of the research that might reasonably be expected to influence willingness to participate, and (ii) explain all other aspects of the research about which participants may inquire at any stage of the study.

Although deception is practiced in some institutions in order to prevent or control participant reactivity, it is forbidden at Northern Caribbean University. An alternative procedure or strategy should be used to prevent participant reactivity.

Freedom to Withdraw

Since research subjects have the right to withdraw from a project at any time, this right should be acknowledged and respected. The informed Consent Instrument should contain statements which instruct the participant or his/her representative about the participant's right to withdraw from the study without incurring any penalty.

Protection from Harm & Debriefing

The researcher is the expert, and it is assumed that he/she is aware of the inherent and potential threat to the physical and the well-being of the participant or the social implications and harm associated with the study. Hence, the researcher should indicate where participants might receive help or advice if problems or questions arise. It may also be prudent to plan and provide detailed debriefing.

Confidentiality

The behaviour exhibited or any information that is given by the research subject should remain confidential. Hence, the procedure(s) that will be used to ensure anonymity and the preservation of confidentiality should be clearly outlined in the research proposal.

Good/Adequate Research Protocol

The research design should be compatible with the research question(s) or hypotheses. Experts in the field of study should agree that the proposed design is adequate, and that its faithful execution will furnish valid and reliable findings. Reviewers will not assume that the research design is valid or feasible. It is the responsibility of the investigators to (i) establish the credibility of the design, (ii) convince the reviewers through logical and persuasive arguments, as well as careful documentation which exhibit a combination of procedural skills and the requisite declarative knowledge that are currently used by the luminaries of the field of study.

Each research proposal should contain a feasible timetable and a reasonable estimate of the cost of the project. Both the cost estimates and the timetable should be placed in the Appendix.

General Subject Recruitment Guidelines

Recruitment of subjects is considered the start of the consent/assent process. Therefore, it is important for researchers to consider how study subjects will be recruited both before the study is initiated as well as throughout the study. Recruitment of research subjects should be equitable and non-discriminatory.

The questions in the IRB application must be answered to describe the proposed study population to be recruited for the research. All materials used to recruit subjects must be submitted to and approved by the IRB. This includes materials such as flyers, posters, brochures, media advertisements (e.g. audio or video taped), and recruitment letters. The IRB must review the final copies of all recruitment materials and not draft versions. For printed advertisements or audio video advertisements, the IRB must review the final version prior to use. Researchers must also state the amount of reimbursement given to subjects to compensate for their time, parking, travel, etc.

Advertisements

The IRB must review and approve the information presented in all advertisements that will be used to recruit potential research subjects and the method used to communicate the information. Advertisements must present information that is adequate, accurate, and balanced so that potential subjects can make an informed decision about possible participation. An appropriate advertisement should:

(a) Provide straight forward and honest information

(b) Specify the project is research

(c) Provide ages and other requirements for eligibility

(d) Clearly state the purpose

(e) Include benefits, if any

(f) State time or other commitment required of subjects

(g) Provide a contact person's name and identify the institution

(h) Indicate where the research will take place

Researchers should be careful to avoid creating advertisements that focus on the amount of reimbursements, use exculpatory language where subjects may be required to give up some of their rights or promise favourable outcomes.

Recruitment of Students

Students are entitled to the same protections and considerations granted to other research subjects. However, there are some considerations such as the perception of coercion to participate or undue influence. Researchers who plan to recruit their own students to participate in research should consider:

i. The study could be completely anonymous.

ii. Student can complete the Evaluation of Instructor Form once the research has been completed.

iii. The Researcher/Professor can collect the data and not use it for research until the course has ended and grading is complete.

iv. The consent form must state the students will have no penalty for refusing to participate.

v. The study should be introduced by a colleague or someone who has no association with the study.

Recruitment of Employees

In cases where employees participate as volunteers in research projects conducted by their supervisors or in which their supervisors are doing the recruiting, they represent a vulnerable population subject to coercion or undue influence. Researchers must ensure that all personnel who participate, even in studies that are minimal risk, do so entirely voluntarily. Special care should be taken when school employees or laboratory personnel participate as subjects in research.

Qualifications of Investigator(s)

The credentials and relevant experience of each investigator should be submitted with the proposal. The documents should show that the investigator(s) are competent and capable of conducting the study in a manner that brings credit to NCU, advance the interest of the investigators, and lead to the development of the field(s) of study.

Letters of Permission & Approval of Sponsors/Agencies

Official affidavits should be submitted if documents of sponsors or agencies will be used in the study. Those letters should be addressed to the Director, JRB, Office of Research and Grants, NCU. They should be signed by appropriate officers of the relevant institution(s). Letters should be submitted before the study begins, or if the study is part of an ongoing project, they should be submitted in reasonable time after the agency gives the investigator permission to use its files.

Dissemination of Findings

Each proposal should contain a description of the reports that will be produced. and their corresponding targets or audience(s). At least two types of report should be developed, namely, (i) a Technical Report that is addressed to the professional or scientific community. (iii a Secondary Report that is addressed to the average citizen.

Non-Human Vertebrate Animal Research Protocol

Experimentation with Non-Human vertebrates should be considered only after careful exploration of alternatives. Such an exploration should look at plausible options such as ethological observation, cell culture, as well as the use of non-invasive or non-intrusive procedures.

The IRB will examine the application and grant permission for the study to begin only after the preceding concern is adequately addressed in the Research Proposal. Accordingly, the following criteria will be used to assess each experimental study in which non-human vertebrates will be used as research subjects outside of their natural habitats.

Criteria

The Research Proposal
The research proposal should contain the usual components (see Steps in Developing a Proposal). Additionally, the research proposal should contain the following:

(a) Analysis of options
Alternatives to the use of nonhuman vertebrates should be critically analysed. This analysis should look at and discuss: possible replacements, reduction of the number of animals to the minimum required for statistical significance testing purposes and, the refinement of the experimental protocols to lessen pain or distress to the animals. It is important to note that the International Rules allow intrusive studies on vertebrate animals and invertebrate animals that have advanced nervous systems only when lower vertebrates or other alternatives are not suitable. Hence, the researcher must justify the use of vertebrates, especially in an era when there are mathematical and computer models, tissue culture and primitive animals.

(b) Storage and Animal Care
The research protocol must outline the plan for the following: procurement, housing, husbandry of laboratory animals. Some of the essential guidelines are presented below.

Procurement

All animals must be legally acquired from reputable animal breeders.

(a) Common laboratory animals must be obtained from licensed laboratory animal breeders. Pet store animals, except fish, are inappropriate because their genetic and nutritional background, as well as disease potential, is unknown. Fish may be obtained locally.

(b) Animals should be healthy and free of diseases that can be transmitted to humans or other animals.

(c) Animals may not be captured from, or released into the wild, without approval of authorized wildlife and public health officials. This authorization should include student identity, species involved, site and method of capture, name of collector and disposition of animals (e.g. released, maintained, and euthanized.)

(d) All animals are classified as laboratory animals on the first day of study. Proper forms, including the **Research Plan,** must be completed and submitted for review and approval by the IRB before experimentation begins.

Housing

The IRB will accept international standards for the housing of laboratory animals. These are shown in for example, the US based standards in two basic Animals Care guides on the care and use of laboratory animals: *Federal Animal Welfare Act,* and the *Guide for the Care and Use of Laboratory Animals.* For farm animals, use the *Guide for the Care and Use of Agricultural animals in Agricultural Research and Teaching (AgriGuide).* Any deviations from these guides must be approved by a veterinary practitioner and the governing IRB.

(a) Animals must be housed in clean, ventilated, comfortable environments compatible with standards and requirements appropriate for the species used. Animals must have adequate lighting, humidity and controlled temperature (with as little variation as possible), and have activities and social interactions of the species (unless individual housing is dictated by experimental protocol and has been pre-approved by IRB). Lighting must be adequately controlled to support proper circadian rhythms.

(b) Because the conditions above are critical, experiments involving small, common laboratory animals (e.g., mice, rats, hamsters, guinea pigs, gerbils, rabbits) are ONLY allowed in an institutional setting or school setting (if environment, housing and husbandry standards are maintained) and not in a home environment. Home environments are not as tightly controlled as institutional settings and therefore, are not appropriate for experimentation. However, non-invasive and behavioural studies involving pets, including fish and livestock may be done at home. Exceptions for behavioural and agricultural research may be granted only by the IRB.

Husbandry

Animals must be treated kindly and cared for properly.

(a) Animals must be given continuous, clean uncontaminated) water and food supply. Food quality should meet the nutritional requirements of the particular

species. Standard laboratory formulations should always be used for common laboratory animals (unless prevented by experimental protocol). Watering and feeding devices should be cleaned frequently.

(b) Proper care must be provided at all times including weekends, holidays, and vacation periods. Animals must be observed DAILY to assess their health and well-being.

(c) Cages, pens, and fish tanks must be cleaned frequently. A healthy absorbent bedding should be used in cages and pens. Hardwood chips are recommended (do not use cedar) and can be obtained from local pet or feed stores. Do not use newspaper or paper towels because inks may be carcinogens, which adversely affect liver enzyme function.

(d) If an unexpected illness or emergency occurs, animals must have proper veterinary medical and nursing care under the direction of a veterinarian.

(e) Research involving stress factors is permitted only when it causes no permanent alteration in the psychological or physical well-being of the animals.

(f) Research on animals involving anaesthetics, drugs, thermal procedures, physical stress, organisms that are pathogenic for humans or other vertebrates, ionising radiation, carcinogens, mutagens, tumors, or surgical procedures must be directly supervised by a Qualified Scientist or Designated Supervisor within a hospital, school, or clinical/research institution approved by the governing IRB. Projects involving any of the above must be reviewed and approved by the IRB and any national or the regional body designated by law to oversee this kind of research. Proper documentation of this approval must be attached to the research proposal. A letter from the mentor (for student research) attesting to this approval is not sufficient.

Students/Faculty are prohibited from doing such research in a home environment, even if institutional housing is not available.

Experimental procedures that cause unnecessary pain or unnecessary discomfort in any vertebrate anima1 (e.g., mammals, birds, reptiles, amphibians, fish), including operant predator/prey experiments, are prohibited.

Use of Toxic Substances

The use **of alcohol, acid** rain, insecticide, herbicide-, and heavy metal in toxicity or behavioural studies on live vertebrates is prohibited. Tissue culture, chicken embryos up to three days before hatching, and invertebrate studies are recommended as alternative models for testing. Weight loss is one significant sign of stress or toxicity. Maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal(s) is 15 percent.

LD5O: LD means lethal dose or death rate. A **death rate of 50 percent or greater in any group or subgroup, by design or as an unexpected** result **of experimental procedure** is **not permitted, and such a project** will fail to **qualify for approval or continuation.**

Research in nutritional deficiency, ingestion, inoculation or exposure to hazardous or reputedly toxic materials or drugs is permitted to proceed only to the point where signs or lesions of the deficiency or toxicity first appear. Appropriate measures must then be taken to correct the deficiency, toxicity, or drug effect, if such action is feasible. If not, the animal(s) must be euthanized. Experiments **designed to kill vertebrate** animals **are not** permitted. **However, experimental designs** incorporating **humane euthanasia** are **permitted.**

Euthanasia

Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted.

Only the Animal Care Supervisor, Qualified Scientist, or Designated Supervisor may perform euthanasia. **Student researchers may perform euthanasia** only in **an emergency.**

Methods of Euthanasia

1. **Acceptable** Methods of Euthanasia: administration **of** barbituric acid derivatives in **conformance with** applicable laws; **inhalation** of gas anesthetic in a well ventilated area**:** induced narcosis with carbon dioxide **or** nitrogen for common laboratory animals; use of MS222 and hypothermia with subsequent cervical dislocation for cold-blooded aquatic species.
2. **Unacceptable** Methods of Euthanasia: injection of air, or any product containing strychnine, curare, succinylcholine or other neuromuscular blocking agents; guillotine, decapitation and cervical dislocation without prior anaesthesia; exhaust fumes; chloroform or ether; stunning blows to the head; microwaves. These methods are unacceptable for research projects regardless of who conducts the procedure.

Changes to the Research Plan

Any proposed changes in Research proposal by the investigator(s) after initial IRB approval must have subsequent IRB approval before such changes are made and before experimentation begins/resumes.

Pathogenic/Hazardous Substances and Dangerous Drugs Protocol

Pathogenic agents, hazardous substances (explosives, flammable liquids, infectious agents, etc.) and dangerous chemicals (drugs, pesticides) may be used in research studies

after the Research proposal and IRB application have been approved by the IRB. The latter will review each proposal and will approve only those projects in which adequate or appropriate precautions have been taken to protect the ecosystem.

Considering that biodiversity of this region, and sustainable economic development of our nations are dependent on the viability of the organisms within their natural habitats, it is essential that all necessary and reasonable precautions are taken to preserve the environment and the organisms that live in it. It is vital therefore, that the research protocol gives an accurate and detailed discussion of the steps that will be used to assure that pathogenic substances, hazardous substances and dangerous drugs are obtained, stored, and disposed of in an acceptable manner by qualified scientists.

The disposal of laboratory wastes is of particular interest to our societies, whose economic viability is inextricably linked with the natural beauty of our tropical ecosystem. It is essential then, that proper techniques are used when working with pathogenic and non-pathogenic substances, which may cause infection in the laboratory; or chemicals, which may cause irreparable damage to the indigenous plant and animal life.

Additionally, drugs which may not be classified as hazardous (i.e. explosives, toxic or flanmab1e) but nonetheless alter the mood or other emotional states of living organisms, should be used only after the proposal is approved by the IRB.

Criteria/Rules

The Review of scientific projects which use pathogenic, hazardous substances and dangerous drugs shall be guided by standard laboratory procedures of chemistry, physics, biology and microbiology. Additionally, the following guidelines will be applied:

The Research Design

The design must indicate that standard laboratory techniques will be used in the study. The research design of studies that use pathogenic substances or potentially infectious substances such as micro-organisms or the liquid or solid wastes of animals, must indicate that the investigators will follow standard microbiological practices defined in, for example, Bio safety in Microbiological and Bio medical laboratories (see the Office of Health and Safety, Centres for Disease Control and Prevention, Website:

Laboratory Cultures

Cultures of organisms which are purchased for experimentation and are certified as non-pathogenic should be labelled, and the identification or label should contain (i) the full Colloquial and Scientific names of the organism(s), (ii) the source of the microorganisms, and (iii) the title of the catalogue and the reference number. Those identifying features, namely, nomenclature, source(s) and reference should be listed in the Research Plan.

Student Investigation

Students may research with pathogenic agents, hazardous substances and dangerous drugs under the direct supervision of an experienced qualified Scientist or a Designated Supervisor in an approved laboratory. Studies which use pathogenic substances as part of the experimental procedure are prohibited in a home environment. Specimens may be collected at home, but the actual experimentation should be done in an approved laboratory setting. The IRB application form shou1d be submitted with the Research proposal whenever students are to perform experiments with pathogenic- substances, hazardous chemicals and controlled substances (such as dangerous drugs).

Additionally, students who are younger than the legal age of 21 should obtain consent from their parents or legal guardian. The Approval Form: Minors (IRB Form) should be attached to the Research Proposal.

Controlled Substances

Researchers must adhere to all published local or international regulations governing controlled substances. The appropriate regulation(s) should be cited in the Research Plan. Also, the relevant letters of permission from Statutory or Regulatory Authorities should be submitted with the application, prior to the commencement of the research. The IRB must approve all research activities in which controlled substances are used before experimentation begins.

Experimental Procedure: Implementation and Changes

The implementation of the experimental procedure approved by the IRB will be monitored by periodical visits to the laboratory by a qualified Scientist whose name does not appear on the list of investigators. Further, changes to the Research Plan after the initial IRB approval must be granted before such changes are made, and before experimentation begins or resumes.

Checklist for Proposal Review by Project Coordinator

(a) Is this a reimbursable grant?	
(b) Is the P.I. sufficiently competent to carry out the investigation?	
(c) Will the P.I. need release time and if so, how much (state an approximate figure).	
(d) How long a period will there be between initiation of project implementation and the availability of results?	
(e) Are project objectives in harmony with overall objectives of the department?	
(f) If animals are involved, are they cared for according to accepted standards?	
(g) If human subjects are included, has approval been obtained from Human Subjects Committee?	
(h) Is the scope of the project within the policy guidelines of the University?	
(i) List all projects in which P.I., Co-P.I., Res. Asso., Res. Asst. are currently involved including name, project, sponsor, funding, percent time or effort, and indicate whether or not all obligations (e.g. reports) have been met for them.	
(j) Are students going to be employed, and if so, how many?	
(k) Are project personnel salaries in harmony with those of other research faculty in the University?	
(l) Can the project absorb personnel from other projects?	
(m) **Scientific Equipment:** Can existing equipment be utilized for this project and new equipment be shared with other investigators?	
(n) **Faculties**: Has adequate and appropriate space been identified for the research? If not, state the constraints.	
(o) Are there special needs to be satisfied (E.g. irradiation facilities) for which the University must accept responsibility?	
(p) If so describe in detail.	
(q) **Service and supplies:** Does the project need special services, furniture, and office equipment not readily available?	
(r) Describe, including estimated cost.	

Applicant's Checklist

The following should be included in the submission for initial review. You may use this list to assist you in ensuring that all requisite documents have been attached; ***not all may apply to you***. Please include the required documents at the end of this form where possible; in the event that a document has to be scanned, a PDF version is acceptable, but please note that you should try to avoid this where possible.

- ☐ Proposal Defense Completed *(for students only)*
- ☐ Cover/Information Letter *(should state if internal funding is being requested for **NCU faculty only**)*
- ☐ Informed Consent Form(s) (*for interviews and focus groups)*
- ☐ Parent/Guardian Consent Forms *(for studies involving minors)*
- ☐ Research Instruments
- ☐ Recruitment Letters
- ☐ Permission Letters
- ☐ Collaboration Letters
- ☐ Conflict of Interest Disclosure
- ☐ Budget ***(required for all research projects)***
- ☐ Signature of Thesis/Dissertation Chair *(for students only)*
- ☐ Signature of Principal Investigator

The following questions should serve as a guide for the reviewer; answers can simply be yes, no, or not applicable. The reviewer should also comment on the proposal indicating the page and paragraph, or instrument, on which comment(s) is/are based.

Reviewer's Checklist for Human Research

1. Is a clear statement of what will be done supplied by the researcher?

2. Is a clear explanation of the involvement of human participants included?

3. Is it very clear that the study will not be harmful or threatening to the participants or others?

4. Has the matter of informed written consent of participants been addressed?

5. Should there be any circumstance which could compromise the voluntary consent of participants (e.g. incentives, captive populations, second relationship), has this been accounted for satisfactorily?

6. Is the process of selecting participants and obtaining permission(s) clearly described?

7. Are the data collection procedures clearly specified and outlined?

8. Have copies of instruments or samples of items to be used, including tests, interview guides, and observational schedules been provided?

9. Have information letters, consent forms, and other attachments as appropriate been included?

10. Has the right to:

    a. not participate been provided?

    b. opt out without penalty, harm, or loss of promised benefit, and the time frame for opting-out been provided? (eg., up to completion of data collection activities, two months after the completion of data collection activities.)

11. In the event of a participant opting out of the study have the opportunities for withdrawal of data been clearly specified?

12. If underage, legally incompetent, or other "captive" subjects/participant are used, is there provision for the right to opt out for:

    a. the subjects
    b. their parents/guardians?
    c. due consent obtained for parent/guardian

13. Is provision made for explaining the nature, length and purpose of the research to the participants and/or guardians?

14. Are the procedures for providing privacy, anonymity, and confidentiality acceptable?

15. Is there clear provision for debriefing of participants if there are limited and/or temporary exceptions to the general requirements for full disclosure of information?

16. If inducements or promises will be offered to participants, are they of such a nature that they do not compromise freedom of consent?

Reviewer's Checklist for Non-Human Vertebrate Animal Research

1. Is the rationale for animal use clear and appropriate?

2. Are there reasons why non-animal models cannot be used?

3. Is there justification for the appropriateness of the species selected?

4. Is the number of animals to be used in the proposed research adequately justified?

5. Are the facilities for the care of the animals during the study adequate?

6. Has the method of euthanization been clearly described?

7. Is the method for carcass disposal appropriate?

8. (a) Does the proposed research involve administration of hazardous chemicals, carcinogenic, cytotoxic, infections agent, or biological toxins to the animals?

   (b) If so, have the procedures required for the safe handling and disposals of contaminated animals and associated materials been clearly described?

Reviewer's Checklist for Pathogenic/Hazardous Substances and Dangerous Drugs

1. Will the research activities impact negatively on the environment?

2. If "no" to item 25, will there be efficient recycling procedures and/or use of recycled or recyclable materials?

3. Is there a preference for the purchase of product and services that cause the least harm to the environment?

APPENDIX A

DESCRIPTIONS OF ROLES FOR PROJECT PARTICIPANTS

A. The Department Head/ Project Coordinator.

The role of the department head is one of leadership, guidance and coordination of all research activities being carried out in the department. The Department Head should be familiar with personnel and the project objectives, and participate in the evaluation of project objectives.
Department chairs or their designees are responsible to review and attest to a protocol's scientific validity before it is submitted to the IRB for review and approval. The review and attestation at the department level should be undertaken with care, and chairs are encouraged to utilize expertise within the department to ensure appropriate peer review of a protocol before it is submitted to the IRB.

Departmental chairs or their designees are required to:

(a) Review all IRB applications and their protocols submitted by all faculty, staff, and students through their department;

(b) Assure the IRB that applications meet IRB minimum requirements;

(c) Attest that the proposed research is scientifically valid and appropriate; and

(d) Sign-off on the IRB application indicating departmental/school approval and forward to the IRB for review and approval.

(e) Review and approve the hiring of project personnel and various expenditures in connection with project implementation.

(f) Participate in evaluation of project objectives and approval of annual progress reports to ensure these meet acceptable standards.

B. Principal Investigator

The principal investigator (P.I.) should hold a terminal degree, except in areas where a MSc. is regarded as such and preferably with a good combination of training and experience. The protection of human subjects in research is the shared responsibility of Principal Investigators (PIs), sponsors, and the IRB. But the ultimate responsibility for the safety and welfare of subjects rests with the PI. In developing research studies, PIs must:

(a) Design studies that are scientifically sound and that will yield valid results.

(b) Submit the IRB application along with the study protocol to the IRB for review and approval prior to beginning any research activity.

(c) Be appropriately qualified to conduct the research.

(d) Comply with international laws governing the ethical conduct of research, local laws and NCU policies, including disclosure of any potential conflict of interest.

(e) Properly obtain and document consent before research is initiated, if applicable.

(f) Conduct the study according to the IRB application and protocol approved by the IRB and with the highest ethical standards.

(g) Ensure that the research is conducted responsibly and that all research personnel are adequately trained and supervised.

(h) Disclose to the Institutional Review Board any potential conflict of interest.

(i) Report any new information, modification, non-compliance with the protocol or IRB policies and procedures, or unanticipated events or problems involving risks to subjects or others promptly.

(j) Ensure that the rights of subjects are protected.

(k) Make adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

(l) Honour all agreements made as a part of the approved research (e.g. reimbursement to subjects, providing results of research/tests to subjects).

(m) Meet all reporting requirements of the Office of Research & Grants, the IRB and the funding agency and notify the IRB in writing upon completion of the research activities.

(n) `Submit reports in a timely manner for continuing review of ongoing research activities.

(o) Ensure that there are adequate resources to carry out research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members (for example, co-investigators) and support staff such as technicians, administrative staff, equipment, and space.

(p) Ensure that research staff are qualified (e.g. including but not limited to appropriate training, education, expertise credentials, and when relevant privileges) to perform procedures assigned to them during the study.

(q) Supports the department head in coordinating the project, and inter alia,

(r) Initiates purchase requests for the purchase of goods and services.

(s) Ensures timely expenditure of project funds to facilitate progress of the research.

(t) Promotes the research and the University locally and internationally through:

- attendance at appropriate meetings, conferences, symposia
- publishing of singly or jointly authored publications; preferably in refereed scientific journals, trade journals or in publications originating at NCU; ensures that the study provides opportunity for student experiential learning and motivation.

(u) Ensures good record keeping in terms of expenditures and documentation required for reviewers, whether annually or otherwise.

C. **Faculty Advisors**

In undergraduate student research, the Faculty Advisor is named as the Principal Investigator and provides supervision and guidance to the student researcher (the Student PI). When a faculty member agrees to be a Faculty Advisor, at a minimum he or she agrees to the following responsibilities:

(a) Oversees the design and conduct of the study

(b) Ensures that the student/staff member assuming duties are well-trained and competent

(c) Reviews IRB application and protocol prior to submission to the IRB

(d) Provides guidance in the protection of research subjects

(e) Assures timely submission of continuing review, amendments, and reporting to the IRB

(f) Works with student/staff researcher to identify revisions warranted by unexpected events/circumstances

(g) Is accessible to student during the active research phase

(h) If applicable, advises and assists students with presentations and manuscript preparation

D. Co-principal investigator (Co-P.I.)

(i) Academic qualification similar to those of the P.I.; works closely with P.I. in the implementation of the project objectives.

(ii) Supervises designated staff and students working on the project.

(iii) Performs the duties of the P.I. when it becomes necessary.

(iv) Contributes intellectually to the execution of the project

E. Research Associate

The individual may hold a terminal degree or a M. Sc. degree or equivalent in the area of study. The research associate may be a full-time teaching or research faculty member with experience and training in the area of research. As regards duties and responsibilities, the research associate reports to the P.I. or Co-P.I. under whose direction he/she carries out tasks and activities related to project implementation. This individual may at times supervise research assistants, undergraduate students or supporting staff when necessary.

F. Research Assistant

A research assistant usually holds a Bachelor of Science. or Master of Science degree or equivalent, and often is a teaching assistant in the department. The research assistant reports to the P.I. or his/her designee and performs tasks as directed by the P.I. He/she may supervise undergraduate or support staff working on the project.

G. Support Staff

This category may include secretarial help drawn from undergraduates wanting part-time employment, or individuals needing a full time job. The skills required are mainly computer and secretarial science. The individual reports to the P.I. or his/her designee.

- Handles the office routine- correspondence, filing, routing, receiving/recording messages and preparing purchase, travel and payroll request.

- Assists with monitoring the expenditure of project funds.

- Any other tasks delegated by the P.I. from time to time that are related to project implementation.

APPENDIX B

IRB APPLICATION FORMS

Section 1 of the form is the same for all types of research. Sections two (2) and three (3) differ based on the type of review needed (i.e. Human Subject, Non-Human Vertebrate, or Pathogenic/Hazardous Substance).

NORTHERN CARIBBEAN UNIVERSITY
OFFICE OF RESEARCH AND PUBLICATIONS
RESEARCH ETHICS REVIEW

Ia. Reviewer's Checklist for Human Research Application

(PI Name and Project Title to be filled in by applicant)
Principal Investigator -
Project Title -

REVIEWER'S ASSESSMENT	**YES**	**NO**	**N/A**
1. Is a clear statement of what will be done supplied by the researcher?	☐	☐	☐
2. Is a clear explanation of the involvement of human participants included?	☐	☐	☐
3. Is it very clear that the study will not be harmful or threatening to the participants or others?	☐	☐	☐
4. Has the matter of informed written consent of participants been addressed?	☐	☐	☐
5. Should there be any circumstance which could compromise the voluntary consent of participants (e.g. incentives, captive populations, second relationship), has this been accounted for satisfactorily?	☐	☐	☐
6. Is the process of selecting participants and obtaining permission(s) clearly described?	☐	☐	☐
7. Are the data collection procedures clearly specified and outlined?	☐	☐	☐
8. Have copies of instruments or samples of items to be used, including tests, interview guides, and observational schedules been provided?	☐	☐	☐
9. Have information letters, consent forms, and other attachments as appropriate been included?	☐	☐	☐
10. Has the right to:			
(a) not participate been provided?	☐	☐	☐
(b) opt out without penalty, harm, or loss of promised benefit, and the time frame for opting-out been provided? (e.g., up to completion of data collection activities, two months after the completion of data collection activities).	☐	☐	☐
11. In the event of a participant opting out of the study have the opportunities for withdrawal of data been clearly specified?	☐	☐	☐
12. If underage, legally incompetent, or other "captive" subjects/participant are used, is there provision for the right to opt out for			
(a) the subjects	☐	☐	☐
(b) their parents/guardians?	☐	☐	☐

(c) due consent obtained for parent/guardian	☐	☐	☐
13. Is provision made for explaining the nature, length and purpose of the research to the participants and/or guardians?	☐	☐	☐
14. Are the procedures for providing privacy, anonymity, and confidentiality acceptable?	☐	☐	☐
15. Is there clear provision for debriefing of participants if there are limited and/or temporary exceptions to the general requirements for full disclosure of information?	☐	☐	☐
16. If inducements or promises will be offered to participants, are they of such a nature that they do not compromise freedom of consent?	☐	☐	☐

Ib. Reviewer's Checklist for Animal Research

17. Is the rationale for animal use clear and appropriate?	☐	☐	☐
18. Are there reasons why non-animal models cannot be used?	☐	☐	☐
19. Is there justification for the appropriateness of the species selected?	☐	☐	☐
20. Is the number of animals to be used in the proposed research adequately justified?	☐	☐	☐
21. Are the facilities for the care of the animals during the study adequate?	☐	☐	☐
22. Has the method of euthanization been clearly described?	☐	☐	☐
23. Is the method for carcass disposal appropriate?	☐	☐	☐
24. (a) Does the proposed research involve administration of hazardous chemicals, carcinogenic, cytotoxic, infections agent, or biological toxins to the animals?	☐	☐	☐
(b) If so, have the procedures required for the safe handling and disposals of contaminated animals and associated materials been clearly described?	☐	☐	☐

Ic. Reviewer's Checklist for Environmental Issues

25. Will the research activities impact negatively on the environment?	☐	☐	☐
26. If "no" to item 25, will there be efficient recycling procedures and/or use of recycled or recyclable materials?	☐	☐	☐
27. Is there a preference for the purchase of product and services that cause the least harm to the environment?	☐	☐	☐

Comments: ……

……..

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……..

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……..

Reviewer's Signature: ……

Date: _____

IRB Human Subjects Application form

NORTHERN CARIBBEAN UNIVERSITY
OFFICE OF RESEARCH & GRANTS
INSTITUTIONAL REVIEW BOARD (IRB)
HUMAN SUBJECTS APPLICATION FORM

***DO NOT* DELETE OR CHANGE ANY SECTION OF THIS FORM.**
Any evidence of tampering with the format or contents, other than completing the appropriate areas, will be seen as an attempt at dishonesty and will be treated as such.

There are five (5) categories of approval for which you may apply:

- ***Exempt Review*:** Projects that ***DO NOT include human or non-human vertebrate animal subjects.*** For example, persons in IT working on an algorithm to streamline online entry of data, or persons in Biology working on invertebrate subjects, or persons in religion looking at a manuscript in ancient text.
- ***Expedited Review*:** Projects that require a quick response due to deadlines with grant funding or graduation.
- ***Full Review*:** All projects that are being reviewed for the **first time** fall in this category. Projects seeking funding (NCU faculty/staff ONLY) and have no ethical issues for consideration also fall in this category.
- ***Modification Review*:** In the event that a previously submitted project has been modified, this category would apply.
- ***Renewal Review*:** In the event that the time given for ethics approval has expired (as in the case with **all graduate projects** which are only **approved for only one year from the date of approval**), an application for renewal must be submitted.

You are not required to print the document, **ONLY** the signature page; this should then be sent to the office of research and grants. Proposals should be submitted by the **research coordinator (advisor),** or the **administrative assistants within the colleges or school**. No proposal should be submitted by students. **For student proposals**, before submitting the documents save/name the document using the student's name and ID number. ***For example: Mary Buckingham 17008910 IRB Application***.

Be detailed in your response to the questions. This will provide the board with the necessary information to determine the outcome of your application. Failure to do this will result in delays in processing your application.

Definition of Terms

***Principal Investigator (PI)*:** The person in charge of the research project and is responsible for all activities that occurs therein.

***Co- Principal Investigator (Co-PI)*:** A person who shares in the responsibility of directing the research project.

***Investigator*:** A person tasked with carrying out the research activities on a project.

***Conflict of Interest Disclosure*:** Where an individual has one or more significant financial (or research) interest(s), and where these interests have the potential to taint or impact the conducting or reporting of the current project being executed, a statement outlining this should be included.

***Annotated Budget*:** Include a section named "Annotations" that explains **in detail** how the figures are calculated, so that the reviewer can be convinced of the viability of the project and the preparedness of the researchers to conduct said project. In the event that a project will have no overhead costs associated with it, materials and services being donated should be accounted for and should be listed as budgeted items.

NORTHERN CARIBBEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD
RESEARCH ETHICS REVIEW APPLICATION FORM
FOR HUMAN SUBJECTS

SECTION 1 GENERAL INFORMATION

Research Project/Thesis/Dissertation Title:

Principal Investigator:

Name

Department Affiliation

Degree

Emphasis

Investigator's Address

Contact: ***Office:*** ***Home:*** ***Cell:***

Email Address:

Signature:

Students fill out the following section:

**Students receive approval for only a year. Subsequently an application for renewal must be submitted.*

i. Is this research part of your graduate thesis/dissertation? Yes ☐ No ☐
ii. Indicate source of funding. NCU ☐ NON-NCU ☐ *Specify:*
iii. Expected Start Date:
iv. Expected Completion Date:

SECTION 2 RESEARCH TEAM, SITE & FUNDING

- ☐ NCU Faculty
- ☐ NCU Administrator
- ☐ NCU Staff
- ☐ NCU Student
- ☐ Other *(specify)*

Co-Investigators:

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Contact			
Email Address			
Organization			

Research Assistant Information *(if applicable)*			
	Research Assistant 1	**Research Assistant 2**	**Research Assistant 3**
Name			
Mailing Address			
Phone Number			
Email Address			

Site Information

Will the study be conducted at a non NCU site? Yes ☐ No ☐

If "Yes" complete the following for non-NCU site(s). Please affix an additional document if there are more sites than this form allows you to document.

	Site 1	**Site 2**	**Site 3**
Site Name:			
Address:			
Phone Number:			

Please affix documentation which indicates permission to conduct the research at non-NCU sites. These include permission letters.

Collaborative Research Information

- Are other organizations/institutions participating in this research? Yes ☐ No ☐
- Was this proposal submitted to another IRB? Yes ☐ No ☐

If "Yes" please affix a copy of the approval letter.

	Institution 1	**Institution 2**	**Institution 3**
Name of Institution			
Contact Person			
Position			
Contact Number			

Funding Information

- Funding status: Unfunded ☐ Funding applied for ☐ Funded ☐
- Type of Funding: Grant ☐ Fellowship ☐ Internal (NCU) ☐
- Source of Funding: _____
- Award Amount: _____

*Please attach a **detailed annotated** budget*

Declaration by Principal Investigator/Student

By signing or typing my name below, I certify that I have completed the NIH training in Human Research, (https://phrp.nihtraining.com/users/login.php) and I agree to comply with all regulations governing research with human participants. I acknowledge that I am responsible for requesting any modifications to this protocol for review and approval by the IRB prior to implementation.

I agree to report any adverse events immediately to the IRB and to comply with all requests to report on the status of a study if so requested. I agree not to recruit participants or collect data until I receive an approval letter from the IRB granting permission to do so.

Name: _____ **Signature:** _____

Declaration by Dissertation / Thesis Chairs and Co-investigators

I/We agree to uphold the same standards and abide by all regulations as stated above.

Name: _____ **Signature:** _____

Name: _____ **Signature:** _____

Name: _____ **Signature:** _____

SECTION 3 PLEASE COMPLETE FOR HUMAN SUBJECT(S) RESEARCH APPROVAL

Abstract ***(Write a summary of 250 -500 words describing the background, purpose, significance, methodology, and expected outcomes of the project).***

1. Indicate whether this project involves any of the following participant populations/subjects or materials:

- ☐ Economically or educationally disadvantaged participants
- ☐ Cognitively impaired or mentally disabled participants
- ☐ Prisoners
- ☐ Pregnant women
- ☐ Minors (persons under 18)
- ☐ Vertebrate animal(s) (including tissue, fluid etc.)
- ☐ Biological/chemical/radiation hazardous material
- ☐ None of the above
- ☐ Other (*specify)* _____

2. Using non-technical language, describe the research process you will employ. Please outline *in detail* the steps in the research study in order as they will occur after consent has been secured.

3. List and/or describe your sources of data collection/ instruments. Please attach a copy of each to the completed form.

4. Describe the characteristics of the participants, including age range, gender and whether

they belong to any vulnerable population group(s).

5. Describe the process of selecting subjects. Also clearly indicate the number of subjects selected.

6. Describe the benefits of the research to the subjects, where applicable, and the contribution to the body of knowledge.

7. Are there any risks or disadvantages for the subjects? How will these be minimized and monitored?

8. Detail the steps which will be used in the informed consent process.

9. How will the subject's privacy and confidentiality be protected?

FOR OFFICAL USE ONLY

Approval granted after:		***Approval denied after:***	
Exemption Review	☐	Exemption Review	☐
Expedited Review	☐	Expedited Review	☐
Full Review	☐	Full Review	☐
Modification Review	☐	Modification Review	☐
Renewal Review	☐	Renewal Review	☐

Name: _____ **Signature:** _____ **Date:** _____

Name: _____ **Signature:** _____ **Date:** _____

Non-Human Vertebrate Animal Application Form

SECTION 3 **PLEASE COMPLETE FOR VERTEBRATE ANIMAL SUBJECT**

Abstract ***(Write a summary of 250 -500 words describing the background, purpose, significance, methodology, and expected outcomes of the project).***

1. **Using non-technical language, describe the research process you will employ. Please outline *in detail* the steps in the research study in order as they will occur after consent has been secured.**

2. **Justify the use of vertebrate animals in conducting this research. Are there less invasive methods which could supply the required information? Are there other species which could be used in obtaining answers to the experimental question(s)?**

3. **What methods will be employed to minimize pain and discomfort to the animal(s)? List medications and attach license where applicable.**

4. **What precautions will be taken to ensure safety of personnel who handle animal(s)? Do personnel have adequate training and experience in the procedures? How will accidents or emergencies be handled?**

5. **Does the environment in which the animals are housed and procedures carried out have adequate ventilation and direct airflow from personnel to the animal cages?**

6. **How will the animals or carcasses be managed post-procedurally?**

7. **Describe the conditions in which the animals will be housed.**

8. **How many animals do you anticipate would be necessary to obtain significant results? Justify your response.**

9. **How will the animals be transported?**

10. **Will the services of a certified veterinary practitioner be employed? Please supply the following information for this person.**

Pathogenic/Hazardous Substances and Dangerous Drugs Application Form

SECTION 3 PLEASE COMPLETE FOR USE OF BIOLOGICAL/CHEMICAL/ RADIATION HAZARD

Abstract ***(Write a summary of 250 -500 words describing the background, purpose, significance, methodology, and expected outcomes of the project).***

1. **Using non-technical language, describe the research process you will employ. Please outline *in detail* the steps in the research study in order as they will occur after consent has been secured.**
2. **List the hazardous material to be used and give rationale for its/their use.**
3. **Are there alternative procedures or approaches to answering the experimental question(s)?**
4. **Describe the environmental conditions in which the materials will be used.**
5. **Describe the source(s) of the material(s) and the mode(s) of transportation.**
6. **Describe the storage and security conditions at NCU.**
7. **How will the used material be discarded?**
8. **Has personnel received adequate training in the handling of the material, and are they sufficiently experienced? Be detailed in your response.**
9. **How will personnel exposure be monitored, and what procedures will be followed in the event of an emergency?**
10. **What records will be kept, and how and where will they be kept?**

APPENDIX C

SAMPLE DOCUMENTS TO ACCOMPANY IRB APPLICATIONS

The following forms are taken from The World Health Organization website; page title "Research Policy" under Informed Consent Form Templates http://www.who.int/rpc/research_ethics/informed_consent/en/

Other forms and/or letters may be needed. Samples of these are easily retrieved from the World Wide Web.

Informed Consent (Qualitative Studies)

This template is for research interventions that use questionnaires, in-depth interviews or focus group discussions)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

- square brackets indicate where specific information is to be inserted
- bold lettering indicates sections or wording which should be included
- standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

(Example: This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".)

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the research

Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research

interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one-hour interview).

Participant Selection

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop

participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive at this Centre will continue and nothing will change.
OR
The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures

A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to…. :)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

(Example 1 (for focus group discussions)

take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.
The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.
We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask….. ***We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.***
The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The

tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)

participate in an interview with [name of interviewer] or myself.
During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)

fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one-month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview" OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions, you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.])

The following applies to focus groups:

Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that the we cannot guarantee complete confidentiality of information that you share with us in a group discussion Do you have any more questions?*

Sharing the Results

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research

team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local IRB that has approved the proposal. State also that the proposal has also been approved by the WHO ERC.

(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____ .)

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you*

know that I have given the contact details of the person who can give you more information about the study? Etc.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have been invited to participate in research about malaria and local health practices.

(This section is mandatory)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

If illiterate [1]
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **Thumb print of participant**

[1] A literate witness must sign (if possible, this person should be selected by the participant and shoul
connection to the research team). Participants who are illiterate should include their thumb print as well.

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Informed Consent (Clinical Studies)

(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

    - square brackets indicate where specific information is to be inserted

    - bold lettering indicates sections or wording which should be included

    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

[Name of Principle Investigator]

[Informed Consent form for _____ _____]

Name the group of individuals for whom this informed consent form is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "……")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic).

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1. give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2. provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3. explain the known experience with this drug

4. explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research

experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. <u>Unfamiliar Procedures</u>

This section should be included if there may be procedures which are not familiar to the participant.

<u>If the protocol is for a clinical trial</u>:

(1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example: Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about, or that is bothering you about the research, please talk to me or one of the other researchers)

(2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

(3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

<u>If the protocol is for clinical research:</u>

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take about ……..this much blood in x number of weeks/months. At the end of the research, in 1 year, any leftover blood sample will be destroyed.)

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve….)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____ (number of) days, for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period, he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example: We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part

in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR

(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The

understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____ (Day/month/year)

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ ***AND*** ***Thumb print of participant***

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Parent/Guardian Consent Form (Qualitative Studies)

(For use with Participant Observation, Focus Group Discussions, Interviews, and Surveys)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

    - square brackets indicate where specific information is to be inserted

    - bold lettering indicates sections or wording which should be included

    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the research titled. "What do we want: Adolescents and health systems ")

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

(Example: I am X, and I work at Y organization in _____. I am doing some research which might help your clinic/hospital do more to help teenagers become and stay healthier. In our research we will talk to many teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose

Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

(Example: It is possible that the clinics and the hospital in this region are not providing some of the services that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including sexual and reproductive health. We will invite them to share their knowledge and understanding with us so that we can find ways of meeting their needs at the local clinics and hospital.)

Type of Research Intervention

Briefly state the intervention. This will be expanded upon in the procedures section.

(Example: A questionnaire OR a focus group OR an interview)

Selection of Participants

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

(Example: We want to talk to many teenagers about their health and what information or services they want for themselves. One part of health that we want to talk to them about is sexuality. We would like to ask your daughter/son to participate because she/he is a teenager and lives in this region.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking your child to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the

beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

(Example: You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. And it can be especially hard when the research includes sensitive topics like sexuality. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.)

- ***Examples of question to elucidate understanding:*** *If you decide not to allow your child to take part in this research study, do you know what the options for him are? Do you know that your child does not have to take part in this research study, if you do not wish so? Do you have any questions?*

Procedure

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

(Examples:

1) the following applies only to focus group discussions*:*

Your daughter/son will take *part in a discussion with 7-8 other teenagers, or a mix of teenagers and social service workers from the community. The girls and boys will be in separate groups. This discussion will be guided by [give name of moderator] or me.*

2) the following applies only to interviews*:*

Your daughter/son will participate in an interview with [name of interviewer] or myself.

3) the following applies only to questionnaire surveys*:*

Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires]. ***OR*** *The questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.)*

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that if researchers talk to their children about sexuality it may encourage them to explore sexual activities with their peers. Other

concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

(Examples:

1) The following applies only to focus group discussions:

The group discussion will start with me, or the focus group guide (use the local word for group discussion leader), making sure that the participants are comfortable. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about sexual and reproductive health as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after ____period of time.]

2) The following applies only to interviews:

If your daughter does not wish to answer any of the questions during the interview, she may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after _____period of time.]

3) The following applies only to questionnaires and surveys:

If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after _____period of time.])

Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

*(Example: We are asking your child to participate in an interview which will take about 1 hour of her/his time. We can do this outside of school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time.***)**

- ***Examples of question to elucidate understanding:*** *If you decide that your child can take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending a transport to pick up your child from your home? Do you know how much time will the discussion with other people take? If you agree that your child can take part, do you know if he/she can stop participating? Do you know that your child may not respond to the questions that he/she does not wish to respond to? Etc. Do you have any more questions?*

Risks and Discomforts

Explain any risks or discomforts including any limits to confidentiality.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking your son/daughter to share with us some very personal and confidential information, and he/she may feel uncomfortable talking about some of the topics. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she doesn't wish to do so, and that is also fine. He/she does not have to give us any reason for not responding to any question, or for refusing to take part in the interview"

OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that your son/daughter may share some personal or confidential information by chance, or that he/she may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.)
Your daughter/son may choose to tell you about the interview and the questionnaire but she/he does not have to do this. We will not be sharing with you either the questions we ask nor the responses given to us by your child.)

Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

(Example: There will be no immediate and direct benefit to your child or to you, but your child's participation is likely to help us find out more about the health needs of teenage girls and boys and we hope that these will help the local clinics and hospitals to meet those needs better in the future.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(Example: Your daughter/son will not be provided with any payment to take part in the research. However, she/he will be given with [provide a figure, if money is involved] for her/his time, and travel expense (if applicable).)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality:

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

(Examples:

Because something out of the ordinary is being done through research in your community, it will draw attention. If your daughter/son participates, she and you may be asked questions by other people in the community.

We will not be sharing information about your son or daughter outside of the research team. The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child

will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.].

The following applies to focus groups*:*

We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about your child will remain confidential? Do you understand that the we cannot guarantee complete confidentiality of information that your child shares with us in a group discussion Do you have any more questions?*

Sharing of Research Findings

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

(Example: At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. A written report will also be given to the participants which they can share with their families. We will also publish the results in order that other interested people may learn from our research.)

Right to refuse or withdraw

Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

(Example: You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not affect either your own or your child's future treatment at the Centre here in any way. You and your child will still have all the benefits that would otherwise be available at this Centre. Your child may stop participating in the

discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.])

- *Example of question to elucidate understanding: Do you know that you do not have to allow your child take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

PART II: Certificate of Consent

Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview and one questionnaire **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____ (Day/month/year)

If illiterate

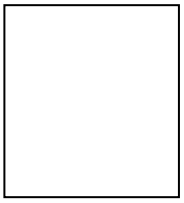
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1.

2.

3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant ____

Print Name of Researcher/person taking the consent_____
An Informed Assent Form will ____ OR will not ____ be completed.

Parent/Guardian Consent Form (Clinical Studies)

(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4 This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

4. In this template:

    - square brackets indicate where specific information is to be inserted

    - bold lettering indicates sections or wording which should be included

    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

    TEMPLATE ON FOLLOWING PAGE

[Name of Principle Investigator]

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X)

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form
has

PART I: Information Sheet

Introduction

Briefly state who you are. and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country.

I am going to give you information and invite you to have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose

Explain the problem/research question in lay terms which will clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

(Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine).

Type of Research Intervention

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

(An injection OR a series of three injections OR taking a vaccine orally, a biopsy).

Participant selection

State clearly why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

(The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can't assume that the vaccine will be as effective on young children unless we test it on children

We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.)

- ***Example of question to elucidate understanding:*** *Do you know why your child has been identified as a potential research participant? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.)

- ***Examples of question to elucidate understanding:*** *If you decide that you do not want your child to take part in this research study, do you know what your options for him/her are? Do you know that you do not have to accept that your child takes part in this research study? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1. give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.

2. provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3. explain the known experience with this drug

4. explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(The ABX vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exist. While the current vaccine protects only 60% of people who take the vaccine the new one protected more than 80% of the people The new vaccine also protected for a longer time period. We want to compare those two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.

The drug is made by Company AB, who is working with a local hospital to have it tested. It's called a _____type of drug because it helps part of the blood to_____. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.)

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

   (Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.

   One group will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing vaccines without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medicines or treatment is doing, we will find out which vaccine your child is getting and make changes.)

2) involving a placebo, it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

   (A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

   (If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine.".)

Description of the Process – Should this be B?

Describe the process on a step-by-step basis.

(You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child's arm. This will be tested for the presence of substances that help your child's body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising but this will disappear in a few days.

In the next visit, your child will be given either the test vaccine or the vaccine that is currently being used for malaria in this region. Neither you nor we will know, until later in the study, which vaccine your child was given. The vaccine will be given by a trained healthcare worker. After the vaccine, we ask that you and your child stay at the clinic for 30 minutes so that the healthcare worker can observe any immediate changes in the child's mood, and if swelling occurs around the injection site. We will give you and your child juice and something small to eat.

We will ask your child's physician to give us the details of your child's health and illness related information. If you do not wish us to do that, please let us know. However, because your child's health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given….)

In case of a clinical research:

Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Your child will receive the treatment for his/her condition according to national guidelines, etc. The sample will be taken using a local anesthesia which means that only the part of your child that we are taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn't feel pain, etc.)

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ___ years, when the research is completed.

Duration

Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

(The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days, for ____ (number of) hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at anytime and ask to see
[name of nurse, doctor, researcher].
We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

(By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that _____may happen as a result of taking this drug. While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide your child with_____. [explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.])

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the
side effects and risks discussed above.

(By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine your child is receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that your child may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not your child is in the research study? Etc. Do you have any questions?*

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(If your child participates in this research, he/she will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefit for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(You will not be provided any incentive to take part in this research. However, you will be reimbursed with - provide a figure if money is involved - for your lost time and travel expense.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your and your child's travel costs and your time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you and/or your child will remain confidential? Do you have any questions about them?*

Sharing of the results

Your plan for sharing the information with the participants and their parents should be provided.
If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

(The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research).

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

(You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child

losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this Centre will be affected in any way.)

Alternatives to participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

(If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.])

PART II: Certificate of Consent

Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

(I have been invited to have my child participate in research of a new malaria vaccine). **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

Print Name of Participant_____

Print Name of Parent or Guardian_____

Signature of Parent or Guardian _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of parent

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1.

2.

3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

An Informed Assent Form will_____ OR will not _____ be completed.

Informed Assent for Minors

(language should be at a level appropriate to the child's age and development)
This template is written for a pre-adolescent or young adolescent.

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed assent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed assent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

    - square brackets indicate where specific information is to be inserted

    - bold lettering indicates sections or wording which should be included

    - standard lettering is used for explanations to researchers only and must not be included in your assent forms. The explanation is provided in black, and examples are provided in red in italics.

Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for _____]

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

(This informed assent form is for children between the ages of 12 - 16 who attend clinic X and who we are inviting to participate in research Y.)

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you do and clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

(Example: My name is ____and my job is to research and test vaccines to see which work best to stop malaria before it makes someone sick. We want to know if this new vaccine will stop children from getting sick and we think this research could help tell us that.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But

if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain).

Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

(Example: We want to find better ways to prevent malaria before it makes children sick. We have a new vaccine to prevent malaria which we are hoping might be better than the one that is currently being used. In order to find out if it is better we have to test it.)

Choice of participants: Why are you asking me?

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

(Example: We are testing this vaccine on children who are your age - between 12 and 16 years old - who live in a place where there is malaria . We are only testing the vaccine on children who do not have malaria.)

Participation is voluntary: Do I have to do this?

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

(Example: You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it's still okay.

<u>If applicable:</u> If anything changes and we want you to stay in the research study even if you want to stop, we will talk to you first .)

- ***<u>Examples of question to elucidate understanding:</u>*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

I have checked with the child and they understand that participation is voluntary __(initial)

Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?

Include the following section only if the protocol is for a clinical trial:

1. give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2. provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3. explain the known experience with this drug

4. explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The vaccine we are testing in this research is called ABX. It has been tested twice before with adults who do not have malaria but who live in areas where malaria is common. We now want to test the vaccine on teenagers who do not have malaria. This second research is called a "phase 2" trial.

The vaccine ABX is made by Company C. It has very few side effects. It can make you feel tired for the first 24 hours after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no greater risk or other side effects. Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known side effects.)

Procedures: What is going to happen to me?

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

(Example: We are going to test the vaccine by giving some of the children in the research study the new vaccine and the others are going to get the vaccine that is already being used to prevent malaria. Neither you nor the researchers will know which vaccine you were given until after the study is over. By doing the research like this, we can compare which of the vaccines is better without being influenced by what we think or hope the research will show.

If you decide that you want to do this, there will be three things that happen.

1. *In about ten days, you will come to the clinic with your parents and you will get an injection/shot in your arm. This is either the vaccine that we are testing or the vaccine that is usually used to prevent malaria.*

2. *At the clinic we will also give you a mosquito net to take home and sleep under. Maybe you have seen these before. They stop mosquitoes from biting you during the night when you sleep.*

3. *Once a month for six months after that, you will come to the clinic and the nurse will take your temperature. She will also take a little bit of your blood, about three or four drops, from your finger with a finger prick. This might hurt a little but the hurt will go away before very long.*

Altogether you will come to the clinic 7 times over 7 months. At the end of seven months, the research will be finished. I have a picture here to show you what will happen. You can ask me to stop and explain again at any time and I will explain more about the process).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? How many times extra will you have to come if you decide to take part in the research study? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

I have checked with the child and they understand the procedures _____(initial))

Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

(Example: The vaccine is considered safe. It has already been tested on adults and on other children. There has been nothing that has worried us at all. If anything unusual happens to you, however, we need to know and you should feel free you to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the clinic every month for a check-up. If you get sick or have concerns or questions in-between the scheduled visits to clinic, you should let me or the staff nurse know. You don't have to wait for a scheduled visit.)

Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what

may be some of the child's worries, for example, missing school or extra expense to parents.

(Example: There are a few other things that I want you to know.)

The injection might hurt for just a second when it goes into your arm. It might get a little bit red and hard around the place where the injection/needle goes in. That should go away in a day. If it hurts longer than that, or if it stays hard for longer or swells up, tell your parents or me. If you feel bad or strange, tell us.

Sleeping under a mosquito net can be uncomfortable because it can be hot and stuffy.

Sometimes you may not want to come to the clinic to get your blood checked or have your temperature taken. It's important that you try to come. It won't take very long. You will miss a little bit of school - about an hour every month - and we will tell your teacher about that so that she knows it's okay.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

I have checked with the child and they understand the risks and discomforts ____(initial)

Benefits: Is there anything good that happens to me?
Describe any benefits to the child.

(Example: Nothing really good might happen to you. The vaccine may not stop you from getting malaria. But this research might help us to find a vaccine now or later that could help other children. There are a couple of good things if you do decide that you want to do this. You do get regular check-ups with the nurse so that if you are sick, we will know very soon and this can be important. And you will keep the mosquito net which will help keep mosquitoes away from you. Because mosquitoes cause malaria, this is important.)

I have checked with the child and they understand the benefits_____ (initial)

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These expenses may include, for

example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(Example: Because you live quite far from the clinic, we will give your parents enough money to pay for the trip here and (whatever other expense is reasonable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality: Is everybody going to know about this?

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

(Example: We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Compensation: What happens if I get hurt?

Describe to the ability of the child to understand and explain that parents have been given more information.

(Example: If you become sick during the research, we will look after you. We have given your parents information about what to do if you are hurt or get sick during the research.)

Sharing the Findings: Will you tell me the results?

Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have

a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

(Example: When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.)

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You may want to re-emphasize that participation is voluntary and any limits to this.

(Example: You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.)

Who to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

(Example: You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.)

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

- *Example of question to elucidate understanding:* ***Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.***

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must

sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

(Example: I understand the research is about testing a new vaccine for malaria and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a finger prick.)

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below. _____ (initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____

Date: _____
day/month/year

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

Signature of researcher_____

Date_____
Day/month/year

Statement by the researcher/person taking consent

I _____ have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child _____ understands that the following will be done:

1.

2.

3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant _____ (initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

Consent for Storage and Future Use of Unused Samples

Notes to Researchers:

1. **Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:

    - square brackets indicate where specific information is to be inserted

    - bold lettering indicates sections or wording which should be included

    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project: [give name of current research]
- ☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

- ☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.
- ☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant_____

Signature of Participant _____

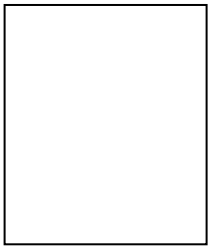
Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant



Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

APPENDIX D

THE NUREMBURG CODE (1949)

International Principles for Human Experimentation

From Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S.G.P.O, 1949–1953.

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

APPENDIX E

A SUMMARY OF THE BELMONT REPORT

Ethical Principles & Guidelines for Research Involving Human Subjects

Reference: Federal Register. 1979 Apr 18;44(76):23192-7. Protection of human subjects: Belmont Report—ethical principles and guidelines for the protection of human subjects of research. U.S. Department of Health, Education, and Welfare.

Boundaries Between Practice & Research

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioural practice is to provide diagnosis, preventive treatment or therapy to particular individuals.

By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

Basic Ethical Principles

- Respect for Persons
- Beneficence
- Justice

Respect for Persons.

The principle of respect for persons divides into two separate moral requirements:

1. Individuals should be treated as autonomous agents, and
2. Persons with diminished autonomy are entitled to protection.

Application of this principle:

Informed Consent. - Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.

Three elements of an informed consent process:

1. Information - The extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge.

2. Comprehension - The manner and context in which information is conveyed is as important as the information itself. Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability.

3. Voluntariness - An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence.

Beneficence.

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.

Two general rules have been formulated as complementary expressions of beneficent actions in this sense:

1. do not harm and

2. maximize possible benefits and minimize possible harms.

In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation.

Application of this Principle

Assessment of Risks and Benefits - A method for determining whether the risks that will be presented to subjects are justified.

Elements of a Risk/Benefit Assessment:

1. **The Nature and Scope of the Risks and Benefits** – Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds

should not be overlooked. Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society).

2. **The Systematic Assessment of Risks and Benefits** - The idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible.

3. Assessment of the justifiability of research should reflect at least the following considerations:

    - Brutal or inhumane treatment of human subjects is never morally justified.

    - Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.

    - When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation).

    - When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits.

    - Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

Justice.

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."

- The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

- Whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Application of this principle

Selection of Subjects – moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Two levels of justice relevant to the selection of subjects:

1. Social - Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

2. Individual - Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favour or select only "undesirable" persons for risky research.

Vulnerable subjects - Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research

solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

APPENDIX F

Guidelines for Faculty Research

In light of the pre-eminence of the research agenda in the strategic priorities of Northern Caribbean University, and in an effort to facilitate the involvement of all members of faculty in the critical process of research within the institution, the following are being recommended:

1. That each member of faculty is required to participate in the process of research, as an important element of personal and professional growth, as well as a primary indicator for advancement in rank within the University.

2. That at least one member of each department should be involved in the formal research process each semester.

3. That while it is preferred that all members of faculty either volunteer or are selected to participate in the formal research process, the same individual may be considered for consecutive selection based on the nature of the project undertaken or being undertaken, and on the availability of others to participate in the process.

4. That the Chair of each department should budget for the employment of one additional member of faculty per each Principal Investigator from that department each year.

5. That the Chair of each department should identify—with the assistance of the individual members of faculty—the order in which researchers are to be selected for participation in the formal research process.

6. That the Chair of each department should ensure that the Principal Investigator for each research is provided with:

   (a) a work load of no more than 50% of the full load during the first semester of his or her selection to allow for the preparation of the proposal

   (b) the second semester of his or her selection to allow for the completion of the study and the preparation of the document to be published

   (c) the relevant resources—such as a student worker, and any other assistance—necessary for the completion of the study

7. That prospective faculty co-researchers from any department be provided with considerations similar to those indicated in Item 6 above.

8. That each participating researcher should, at the end of the designated period, have a completed document that is ready for publication.

9. That in the event the period of research necessary for completion of the study is longer than one academic year—for example, in the case of a longitudinal study—the researcher will return to work, and the terms and conditions renegotiated.

APPENDIX G

Research and Travel Grant for Faculty

Research and Travel Grant for Faculty Engaged in Research with Overseas Collaborators

The Administration of NCU seeks to promote high quality research among faculty and to encourage collaboration between NCU and centers of excellence renowned for research quality and output. In order to support faculty research productivity, this policy was agreed upon for the provision of a Research and Travel Grant of at least five hundred thousand Jamaican dollars each be made on a yearly basis to at least two faculty members. The purpose of this Grant is to support travel and research collaboration with overseas institutions.

Eligibility

The following are guidelines for the selection of faculty members as awardees:

(i) A faculty member who is engaged in on-going research and who will be empowered to pursue more in-depth work;

(ii) A faculty member whose research will require exposure to techniques, procedures and methodologies not currently available at NCU or in Jamaica and whose work is ground-breaking;

(iii) A faculty member who has had limited exposure and wishes to enhance knowledge and research skills;

(iv) A faculty member who has been granted a workload of no more than 50% credit load and the second semester off for the completion of a research project is also eligible to apply

Duration

The period of travel should not ordinarily exceed three months and preferably be done during the summer. For periods lasting more than three months, the faculty member must provide convincing evidence that the work being undertaken requires an extended period of time.

Criteria

The award of the Grant will adhere to the following guidelines:

(i) The faculty member has identified a Department/Institute in another University/Institution and provides the evidence that the overseas institution is

willing to collaborate, has the required expertise and will provide the training and most of the materials required to undertake the research.

(ii) The faculty member prepares a proposal inclusive of a protocol of the research that will be accomplished. The research proposal should include the following: Title; Principal Investigators, Co-investigators, Collaborators and affiliations of each; Abstract, Aim, background, literature review, hypothesis, objectives, materials and methods, data analysis, ethical considerations, risks and benefits, time frame, budget, and references; the role or contribution of the overseas institution.

(iii) Grantees must show how the award of the grant will further enhance the research capabilities and research output at NCU.

Reporting Accountability

Faculty who have benefited from the award are required to provide a report on the outcomes of the research within one month of their return. This should include presentations in relevant Conferences and publication in academic journals. This report should be sent to the Vice-President for Academic Administration through the Dean of the College/School and copied to the Department Chairperson, AVP for Graduate Studies & Research and Director of Research.

An Expense Report with the accompanying receipts should also be submitted to the VP Academic Administration through the Dean of the College/School and forwarded to the Finance department.

Application Procedure

The faculty member must write a letter making a case for their selection for the grant. This letter should be accompanied by the research proposal and a personal expense budget inclusive of return air-fare, accommodation and discretionary spending. Applications should go through the Department Chairperson and Dean of the School/College who will send the application to the Office of Graduate Studies and/or Office of Research and Grants. A special meeting or the Institutional Review Board will be convened to discuss the applications and make recommendations to the University Administration.

The Head of Department and/or Dean must ensure that the faculty member's course assignment is covered by a suitable replacement. The deadline for application is March 31 in the year for which the application is being made.

The University Administration/Finance Committee will determine the number of such grants over and above the stipulated number that will be accommodated each academic year. Any grant money that is not exhausted in the first instant will be available for continuation / completion of the project.

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