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AIDS is still the most serious threat to world health. There has been a dramatic spread of HIV/AIDS from the initial focus in the United States, Europe and Africa to South America and Asia. Although our understanding of HIV/AIDS has increased, only few breakthroughs have been made. Health Education directed at modifying risk behaviour still remains the only way in which the spread of HIV/AIDS can be contained. One important lesson of the last decade is that the problem of controlling HIV and AIDS is not just a question of targeting the virus. It includes tackling social, economic and political issues, and putting AIDS into the broader context of sexuality and gender roles.

Health education programmes will involve mobilization of human resources from government, voluntary services, and non governmental organisations whether on a full time or part-time basis. The first priority for educating others is to learn about the disease so as to dispel the myths and rumours that surround AIDS and answer the searching questions that can be asked by the community.

Scaling up AIDS control activities in Malawi is crucial, and requires the participation of all social and economic sectors. As noted at the 2001 Conference on AIDS in Africa, controlling the disease will only take place with scaling up of requisite resources. In Malawi, pioneer programmes and empowered communities have demonstrated the importance of local responses to HIV and AIDS.

In Malawi where resources are extremely limited, the principles of primary health care, demand that all available, accessible and acceptable resources be applied towards improving health of the people. The AIDS epidemic forces us to review our interests in these principles, partly because of desperate and overwhelming needs, but also because of the imperative to seek diverse solutions that are embedded within the cultural and environmental practices.
There is an urgency to act now. We know that the HIV/AIDS challenge cannot be met without additional resources and information. Furthermore, it cannot be met without considering the contribution from research. Diseases such as HIV/AIDS provide motivation and inspiration through the sharing of experiences, information and challenges.

This document describes the strategy for the health care delivery based on evidence obtained through quality research. The strategy aims to ensure that there is a common understanding of the main priorities for HIV/AIDS research. It sets a framework within which we can all work together and, if necessary respond to new priorities as they emerge. In achieving this aim it is essential that there is robust governance of research and that the public can place confidence in all aspects of the process. The population must benefit from scientific advances, and health care providers need to make the most effective use of the resources at their disposal.

That is why this strategy document seeks to increase the awareness of the need to identify research requirements and to ensure that they are widely known by all those able to play a part. Research represents a significant investment in the future delivery of health and health care. Central to the strategy, is the need to ensure that expenditure on research is as well focused as possible to achieve the objective of improving health and health services for the people of Malawi.

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CHIEF SECRETARY FOR PUBLIC SERVICE
The HIV/AIDS Research Strategy for Malawi (2005-2007) has been prepared with technical assistance of the National Research Council of Malawi at the request of the National AIDS Commission (NAC). The Council developed this Strategy through the appointment of the Taskforce which undertook extensive stakeholder consultations and in-depth literature review. The National AIDS Commission, therefore, acknowledges great efforts of the National Research Council of Malawi and the following members of the taskforce: Professor Yohane Z Nyasulu (member of the National Health Sciences Research Committee); Dr Charles C V Mwansambo (Chairperson of the National Health Sciences Research Committee); Dr Agness Chimbiri (Director of Centre for Reproductive Health); Mr David Chilongozi (Associate Field Director for UNC Project in Malawi); Dr Alister Munthali (Research Fellow of Centre for Social Research and member of the National Health Sciences Research Committee); Mr Blackson F L Matatiyo (Acting Chief Research Officer of the Ministry of Health); Dr Newton Kumwenda (Chairperson of the College of Medicine Research and Ethics Committee); Messrs Alick K Manda, Frade K K Nyondo, Mike G Kachedwa, Hambani A Gausi and Patrick Mphadzula from the National Research Council of Malawi.

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Last but not least, thanks to all colleagues at NAC who were directly collaborating with the National Research Council of Malawi during the time of developing the strategy.

Dr Biswick S M Mwale
EXECUTIVE DIRECTOR

National AIDS Commission
LIST OF ABBREVIATIONS USED

AIDS Acquired Immune Deficiency Syndrome
ARV(s) Anti-retroviral(s)
HBC Home Based Care
HIV Human Immunodeficiency Virus
KAP Knowledge, Attitudes and Practices
NAC National AIDS Commission
NARN National AIDS Research Network
NRCM National Research Council of Malawi
PMTCT Prevention of Mother To Child Transmission
PLWA People Living With HIV/AIDS
STIs Sexually Transmitted Illnesses
VCT Voluntary Counseling and Testing
1.0 INTRODUCTION

Malawi is one of the poorest countries in the world with 65% of the population living below the poverty line. Malawi’s population is 9,933,868 with an average density of 105 persons per square kilometer and intercensal growth rate of 2.0 percent (2000 MDHS). Literacy rate is low and of those who are literate 34% are women and 66% are men. Of the total population, 86% live in the rural areas and are subsistence farmers. The HIV/AIDS epidemic in Malawi is among the most severe in the world. Data indicate that 15% of those aged 15 to 49 years are currently infected with the Human Immunodeficiency Virus (740,000 men and women will develop or already have developed Acquired Immune Deficiency Syndrome). Additionally, available data estimate that 65,000 children aged below 15 years are HIV infected. Alarmingly, about 75% of all AIDS cases occur among people in the most economically productive age group of 20 to 45 years. More than half million Malawians have died of AIDS since the first case of AIDS was diagnosed in 1985.

The principal modes of HIV transmission in Malawi are heterosexual contact and perinatal transmission which account for 90 percent and 9 percent of all HIV infections in the country, respectively. If no antiretroviral drugs are used, the duration between HIV infection and onset of AIDS averages 9 to 10 years and death typically ensues within 1 to 2 years of symptom onset.

Deaths of the most economically productive individuals constitute personal, economic and social tragedies in the lives of surviving family, friends and employers. One needs to appreciate the unprecedented increase in the number of Malawian children under 15 who have been living without one or both parents to understand the impact of the sharp rises in the rates of adult mortality due to the AIDS epidemic. Between 1990 and 2000, the number of orphans grew from about 740,000 to 1.2 million. This has led to increased destitution. In addition, deaths of the most productive individuals
have eroded Malawi’s capacity to attain self sufficiency in human resource development and have significantly contributed to the low productivity in all sectors of the economy.

Several methods that can prevent the spread of HIV/AIDS are known. These include abstinence, condom use, limiting the number of sexual partners (faithfulness), avoidance of sharing razor blades and avoidance of unsterilised injections. However, the knowledge of these prevention methods HIV infection is dependent on gender, age, sexual activity, education and residential characteristics of individuals. The young, sexually inexperienced, rural and less educated men and women are less likely to know all the ways of HIV transmission than their counterparts in the urban.

Nearly every individual in Malawi has been affected by the HIV/AIDS pandemic. However, some sectors of the population are more vulnerable to HIV/AIDS than others. The first population is that of children of HIV-infected parents who are not themselves infected because of the health and social consequences of losing one or both parents to AIDS. The second group is babies born to HIV-infected mothers. Statistics indicate that 20 percent of babies born to HIV-positive mothers will be infected around the time of birth and about one – half of those children will die before their fifth birthday. In addition, the virus can be transmitted from mother to child during pregnancy and during breast feeding. The third group of the vulnerable population is that of the physically challenged. Most messages on HIV/AIDS prevention are presented using communication methods that are not easily accessible and discernible by the deaf and the blind. This means that this population of society has no access to vital information on how to protect themselves from contracting HIV. The fourth group comprises those working in the entertainment and tourism industry and truck drivers. This group is usually susceptible because of staying extended periods of time away from their families. The fifth vulnerable population is that of individuals involved in customary practices that promote the spread of HIV.
A number of individuals, institutions, and organizations have done commendable HIV/AIDS related research in Malawi. However, there has been lack of coordination and knowledge-base, a situation that has led to these stakeholders doing less focused and non priority HIV/AIDS research which in some cases has led to duplication of efforts.

The HIV/AIDS Policy for Malawi calls for the establishment and sustenance of a national HIV/AIDS research agenda. In line with the policy call, this HIV/AIDS Research Strategy for Malawi shall address gaps in the existing research, inform policy and guide HIV/AIDS–related interventions.

The outline of this HIV/AIDS Research Strategy document provides guiding principles of HIV/AIDS research; identifies gaps in HIV/AIDS research and key priority areas in HIV/AIDS research as categorized under epidemiology, socio-cultural issues, prevention, treatment, care and support and mitigation in Malawi. The document also provides for capacity building for HIV/AIDS research in terms of training, infrastructure, institutional support, networking and collaboration. It further outlines proper HIV/AIDS research practices, ethics and mechanisms for monitoring and evaluation as well as dissemination of research results at various levels of society, and how documentation and publication of research results should be done. The document finally provides for financing arrangements for HIV/AIDS research in Malawi.

2.0 OBJECTIVE OF THE STRATEGY

The HIV/AIDS Research Strategy aims at addressing gaps in existing knowledge about HIV/AIDS so as to inform policy, practice and HIV/AIDS- related interventions and contributing to the reduction of HIV transmission in line with the national HIV/AIDS policy. The specific objectives of the strategy are to;
i Promote priority biomedical and social science HIV/AIDS research.

ii Build capacity in HIV/AIDS research through collaboration and resource mobilization

iii Improve the efficiency and effectiveness of the HIV/AIDS programme planners in designing interventions

iv Strengthen the co-ordination of HIV/AIDS research.

v Ensure adherence to ethical and human rights considerations in HIV/AIDS research.

vi Create evidence that would influence appropriate HIV/AIDS policies and programmes for the community and the work place

vii Provide a platform for policy dialogue on HIV/AIDS research

viii Enhance community participation in the planning and execution of HIV/AIDS research

ix Keep track of all the research done on HIV/AIDS.

x Ensure widespread and timely dissemination of HIV/AIDS research results at various levels.
3.0 GUIDING PRINCIPLES OF THE HIV/AIDS RESEARCH STRATEGY

High quality research evidence is the strongest platform from which to mount an effective response to the HIV/AIDS epidemic. Research is essential to improve the design of HIV/AIDS interventions, policies and service delivery. Considerable amount of HIV/AIDS research has been conducted in Malawi. However, most of this research has been donor driven addressing their own priorities with little participation of communities in the planning and execution of the same. Most often, this research is uncoordinated. The scenario has led to duplication of efforts and lack of sustainability of the research programmes. In order to curtail this scenario, the following guiding principles shall be used in the design and conduct of HIV/AIDS research:

3.1 Political Will and Commitment to HIV/AIDS Research
Although research is critical, it is very expensive. Hence, it is important for people in authority to appreciate the role of research and commit funds for execution of HIV/AIDS research. Political will and commitment to HIV/AIDS research shall be nurtured through continuous and systematic dialogue between researchers and policy makers.

3.2 Community Participation in HIV/AIDS Research
The community shall always be involved in the determination of HIV/AIDS research priorities. This includes people who are infected and affected by HIV/AIDS as they are equally a key stakeholder in the HIV/AIDS research discourse and need to be involved during conceptualisation as well as execution of research projects. Often research programmes conceived based on a top-down approach face implementation problems and end up a failure.
3.3 **Non-discrimination and De-stigmatisation in HIV/AIDS Research**

In keeping with the provisions of the Constitution of the Republic of Malawi, the International Human Rights instruments and other relevant statutes, any research that leads to any form of discrimination of people infected and affected with HIV/AIDS will not be approved. Research whose results may lead to discriminating people infected and affected by HIV/AIDS will also not be approved. Ethical review committees will ensure that all ethical issues are properly adhered to at every stage of any research project.

3.4 **Promotion and Protection of Human Rights in HIV/AIDS Research**

The dignity and human rights of the research participants shall be promoted, protected and respected irrespective of their HIV/AIDS status. This will be based on internationally recognized ethical principles, Constitution of the Republic of Malawi and other statutes. Informed Consent of the research participation and publication of any research data shall be sought. Confidentiality shall be maintained to the full extent of the law.

3.5 **Capacity Building in HIV/AIDS Research**

To conduct quality HIV/AIDS research, financial, material and human resources shall be mobilized in order to build capacity for HIV/AIDS research. Integration of capacity building into HIV/AIDS research proposals shall be promoted.

3.6 **Proper Governance of HIV/AIDS Research**

Proper governance of HIV/AIDS research shall be assured. Under this, researchers shall adhere to the established and Government of Malawi recognized research ethics, procedures and guidelines that constitute best practices for HIV/AIDS research. Any research that departs from the requirements of these guidelines shall not be approved.
3.7 Partnerships, Collaboration and Networking in HIV/AIDS Research

HIV/AIDS research that promotes partnership, collaboration and networking both locally and internationally will be encouraged for purposes of capacity building and skills transfer, and optimum resource utilization. Database creation and management shall be supported to ensure sustainable networking in HIV/AIDS research.

3.8 Allocation of Resources to Priority HIV/AIDS Research

Resources shall be allocated according to the identified research priorities. Efforts shall be made to mobilize more resources locally and internationally to address the identified priorities.

4.0 RESEARCH GAPS AND PRIORITY AREAS IN HIV/AIDS RESEARCH

Policy-makers, program implementers and the general population urgently need information that would help them take immediate and effective action to combat the HIV/AIDS epidemic. Following a number of consultations with various stakeholders and review of literature the following research gaps and areas were identified.

4.1 HIV/AIDS Research Gaps

Most of the studies already done are not nationally representative. A careful analysis of these studies as listed under epidemiology, prevention, treatment, mitigation, care and support, socio-cultural and socio-economic themes has revealed some HIV/AIDS knowledge gaps as identified below.

4.1.1 Epidemiology

The prevalence of Hepatitis.

The prevalence of herpes pappiloma virus
Monitoring and evaluation of management of opportunistic infections including ARVs: Traditional vs medical therapy

STI/HIV prevalence in different settings

4.1.2 Socio-cultural

A lot of studies have been done in this area but the following gaps are still a concern;

Knowledge Attitudes and Practices (KAP) study on female condom

Studies in HIV/AIDS Knowledge Attitudes and Practices in the public and private sector

Depth, extent and type of knowledge on HIV/AIDS in the general population

Positive aspects of cultural-based sexual and reproductive health practices, skills and attitudes in relation to HIV/AIDS

Longitudinal ethnographic studies on how HIV/AIDS has contributed to cultural change and people’s perceptions about this.

Impact of gender differences in knowledge on sexual reproductive health

Impact of gender on HIV/AIDS prevention, care and support

Dynamics of safer sex practices

Causes and mitigation of high HIV/AIDS prevalence among married women
Rise in commercial sex workers versus spread in HIV/AIDS

Impact of ARVs on behaviour change (Impact of ARVs on sexual behaviour)

Understanding health workers attitudes towards HIV/AIDS patients

Link between fertility and HIV/AIDS

4.1.3 Socio-economic

Under this, the following gaps have been identified;

Impact of macro-level factors on HIV/AIDS (eg. structural adjustment programmes and food security policies)

Monitoring and evaluation of the impact of ARVs on economic productivity

Impact of HIV/AIDS on productivity of the private and public sector

Estimating human resources attrition rate in public and private sectors

Measuring trends of absenteeism in public and private sectors

Socio-economic implications of ARVs in Malawi

Health care workers motivation versus HIV/AIDS patient outcome

Impact of HIV/AIDS on family functioning
4.1.4 Prevention

Under prevention, the gaps have been identified according to the following sections;

4.1.4.1 Sexually Transmitted Infections/Human Immuno-deficiency Virus/Acquired Immune Deficiency Syndrome (STIs/HIV/AIDS)

Partner notification about STIs/HIV/AIDS

KAP studies on condom use for dual protection

Vaccine research

Microbiocides: Continued search for female control methods for prevention of male to female HIV transmission and STIs.

4.1.4.2 Voluntary Counseling and Testing (VCT)

Gender differences in accessing VCT services

Impact of marital status on access to VCT services

Feasibility of rolling out VCT services in all health facilities in Malawi

Condom use within and outside marriage

Disclosure of HIV status to children and siblings

Role of parents in HIV/AIDS prevention, care and support for their children

Counseling minors
The management of discordant couples

Gender and age-based KAP studies on VCT

Stigmatization and utilization of VCT centers

Coping mechanisms of HIV/AIDS infected people towards stigma, discrimination, care and support

4.1.4.3 Prevention of Mother to Child Transmission (PMTCT)

KAP studies on existing and indigenous breastfeeding alternative feeds and other replacement food.

Role of highly active antiretroviral therapy (HAART) in the PMTCT.

Effectiveness of the current opportunistic infection treatment algorithms

How HIV+ mothers are coping with their sero-status as well as complying with the ARV treatment.

Understanding factors that would promote the uptake of PMTCT services.

Monitoring PMTCT programs in relation to the National Guidelines for the Delivery of PMTCT Services in Malawi.

Role of men and wet nurses in PMTCT

Implications of Nevirapine resistance on the future of ARV therapy in Malawi.

11
Optimal drugs for children and mothers that were exposed to Nevirapine during PMTCT

Effectiveness of PMTCT program in Malawi

4.1.5 Treatment

Under this, the following gaps were identified;

- Simplified and cost-effective test for HIV at the first level health facility (VCT Centre)
- Inexpensive diagnostic test for HIV for the young infant.
- Usefulness of TB blood cultures in fever algorithm for HIV positive patients
- Simplified methods for virologic monitoring
- Needs assessment for ARVs (Demand vs supply of ARVs)
- Capacity assessment for ARV scale-up
- The optimum time to start the HIV infected on ARVs in settings where access to care continues to be limited
- Monitoring resistance patterns on ARVs
- Factors contributing to delayed treatment seeking behavior and adherence to ARVs
- Better understanding of the causes of high mortality on patients on ARVs
Performance of WHO HIV/AIDS disease staging approach: Improvement and validation of WHO staging

The future of free and subsidized ARVs and feasibility of its sustainability

Availability of reference laboratories to monitor performance of ARVs and STIs drugs

Characterization of Opportunistic Infections (OIs) by type and prevalence

KAP studies in Opportunistic Infections (OIs) and traditional therapy of OIs

Comparison of the current first line regimen to other viable regimens

4.1.6 Mitigation, Care and Support

Very few scientific studies on mitigation, care and support have so far been conducted thereby revealing the following gaps as isolated under home-based care and hospital based care;

4.1.6.1 Home-based Care

Coping with orphan care

Assessing care and support for orphans

Impact of nutrition on HIV/AIDS
Monitoring and evaluation of ARV management in communities to verify the criteria being used for ARV roll out plan

Acceptability of referral system

Monitoring and evaluation of HBC activities for PLWA

Issues of compliance and ARVs

The rolling out of the ARVs and its impact on demand for VCT

The rights based HIV/AIDS impact mitigation

4.1.6.2 Hospital-based Care

Understanding health workers attitudes towards HIV/AIDS patients

Integration of family planning services and management of STIs including HIV/AIDS

Link between fertility and HIV/AIDS

Evaluation of newer and simpler HIV testing kits.

Stigmatization and utilization of VCT centers (from provider perspective).

Providers’ perceptions about PMTCT

Monitoring and evaluation of PMTCT protocols for their verification and systematic revisions
The challenges to the provision of VCT services

Monitoring and evaluation of ARV management in health facilities and communities to verify the criteria being used for ARV roll out plan

Impact of HIV/AIDS (increase) on health care delivery systems

Response of health care institutions to HIV/AIDS

4.2 Priority HIV/AIDS Research Areas

Based on the identified gaps, availability of resources and capacity, the strategy outlines the following priority HIV/AIDS research areas on which research shall be focused for the next two years.

4.2.1 Epidemiology

The prevalence of Hepatitis.

The prevalence of herpes pappiloma virus

Monitoring and evaluation of management of opportunistic infections including ARVs: Traditional vs medical therapy

KAP studies in Opportunistic Infections (OIs) and traditional therapy of OIs

STI/HIV prevalence in different settings

4.2.2 Socio-Cultural Aspects

Positive aspects of cultural-based sexual and reproductive health practices, skills and attitudes in relation to HIV/AIDS
Longitudinal ethnographic studies on how HIV/AIDS has contributed to cultural change and people’s perceptions about HIV/AIDS

HIV/AIDS impact mitigation on child, female, male and elderly person headed household

Perceptions and attitudes on sexual relations

Impact of gender on HIV/AIDS prevention, care and support

Impact of ARVs on behaviour change (impact of ARVs on sexual behaviour)

Understanding health workers attitudes towards HIV/AIDS patients

Link between fertility and HIV/AIDS

Knowledge Attitudes and Practices (KAP) study on female condom


Rise in commercial sex workers versus spread of HIV/AIDS

Causes and mitigation of high HIV/AIDS prevalence among married women

Impact of gender on HIV/AIDS prevention, care and support
4.2.3 Socio-Economic Aspects

Impact of existing macro-level factors on HIV/AIDS (e.g. structural adjustment programmes and food security policies)

Estimating staff attrition rate in public and private sectors

Socio-economic implications of ARVs in Malawi

Impact of HIV/AIDS on productivity of the private and public sector

Impact of HIV/AIDS on family functioning

4.2.4 Prevention

Under prevention, the areas have been arranged according to the following sections;

4.2.4.1 Sexually Transmitted Infections/Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (STIs/HIV/AIDS)

KAP Study on female condom

Partner notification about STIs/HIV/AIDS

The condom as a dual method

4.2.4.2 Voluntary Counseling and Testing (VCT)

Role of religion in the fight against HIV/AIDS
Feasibility of introduction of VCT services in all health facilities in Malawi

Role of parents in HIV/AIDS prevention, care and support for their children

Condom use within and outside marriage

The management of discordant couples

Disclosure of HIV status to children and siblings.

Counseling minors

Stigmatization and utilization of VCT centers

Coping mechanisms of HIV/AIDS infected people towards stigma, discrimination, care and support

4.2.4.3 Prevention of Mother to Child Transmission (PMTCT)

Effectiveness of PMTCT programme in Malawi

Role of men and wet nurses in PMTCT

4.2.5 Treatment

4.2.5.1 Anti-retrovirals (ARVs)

TB and HIV/AIDS co-infection management

Optimum time to start HIV infected infants and children on ARVs in settings where access to care continues to be limited.
Implications of Nevirapine resistance on the future of ARV therapy in Malawi.

Optimal drugs for children and mothers that were exposed to nevirapine during PMTCT

Comparing outcomes of people diagnosed as failing by clinical standards versus virologic failure

Comparison of the current first line antiretroviral regimen to other viable regimens

Needs assessment for ARVs (Demand vs supply of ARVs)

Capacity assessment for ARV scale-up

Monitoring resistance to ARVs

The causes of mortality on patients on ARVs

The sustainability of free ARVs

Studies on causes of delay of the development of full blown AIDS after HIV infection

4.2.6 Mitigation, Care and Support

Monitoring and evaluation of ARV management in communities to verify the criteria being used for ARV roll out plan

Acceptability of the referral systems including home based care (HBC)
Stigma, gender and volunteerism in HBC

The rolling out of the ARVs and its impact on the demand for VCT

Providers’ perceptions about PMTCT.

The challenges to the provision of VCT services

Rights based mitigation of HIV/AIDS

Effectiveness/Impact of orphanages

Impact of HIV/AIDS (increase) on health care delivery systems

Response of health care institutions to HIV/AIDS

Coping with orphan care

Assessing care and support for orphans

Youth involvement in care and support

Impact of nutrition on HIV/AIDS

5.0 STRATEGIES FOR HIV/AIDS RESEARCH

HIV/AIDS is an emergency in Malawi, and therefore, it needs prompt action. In order to undertake sustainable HIV/AIDS research in the priority areas as identified in section four, the following key strategies will be adopted;
i Development and strengthening infrastructure for HIV/AIDS research

ii Facilitation of partnerships between researchers, practitioners and the community

iii Establishment of a National AIDS Research Network (NARN) that would facilitate data base creation, management and, information exchange and sharing

iv Improvement of collaboration, partnership and networking among HIV/AIDS researchers

v Ensuring that HIV/AIDS research is culture and gender sensitive

vi Undertaking capacity assessment aiming at identifying needs for effective HIV/AIDS research

vii Employing a mix of research methods including clinical trials, qualitative interviews, periodic surveys, cohort, comparative, longitudinal and modeling intervention studies.

viii Maximization of opportunities for participation in vaccine research trials

ix Improvement of mechanisms for dissemination of research findings

6.0 CAPACITY BUILDING FOR HIV/AIDS RESEARCH

In order to promote sustainable and quality HIV/AIDS research in Malawi, capacity building becomes one of the key strategies and
areas that require specific attention. There are a number of institutions in Malawi which are providing training and research services in HIV/AIDS related issues. Among these are University of Malawi, University of Mzuzu and Malawi College of Health Sciences. In addition, there are international research institutions such as Welcome Trust, Johns Hopkins, UNC and Karonga Prevention Study. However, the capacity of local institutions is vaguely known unlike their international counterparts. Hence, the need for the National AIDS Commission to commission capacity assessment for HIV/AIDS research and training for these institutions and identify appropriate support due to them. The assessment would cover issues that include type of training and extent to which it covers HIV/AIDS research training needs.

In achieving appropriate capacity for HIV/AIDS research, the strategy is calling for the following:

6.1 Infrastructure Development

6.1.1 Strengthening institutional capacities

Problems regarding the management and distribution of ARVs because of lack of effective infrastructure is a concern. There is, therefore, need for the development of infrastructure for the management of ARVs.

6.1.2 Research Infrastructure

In order to conduct quality research, efforts shall be made to develop and/or strengthen requisite research infrastructure such as laboratories and informatics.

6.1.3 Establishment of a National Aids Research Network

To promote the sharing of information and experiences, individuals and institutions involved in HIV/AIDS related research shall be
mobilized to be on a national network. The network shall also be a forum through which collaborative research projects in priority areas shall be developed and supported. The National Aids Commission shall facilitate the establishment of this network.

6.1.4 Establishment of the HIV/AIDS Research Centre of Excellence

Efforts shall be made to establish the HIV/AIDS Research Centre of Excellence to which all HIV/AIDS researchers will be affiliated. The center will promote scientific excellence in HIV/AIDS research. Among the key functions of the centre will be the commissioning of priority research as well as the promotion of advocacy, partnership, collaboration and networking in HIV/AIDS research at national and international levels.

6.1.5 Strengthen the Capacity of the National Research Council of Malawi and its Affiliate

The capacity of the umbrella research body and all institutions affiliated to it needs to be strengthened in order to effectively advise and monitor HIV/AIDS research.

6.1.6 Strengthening Ethical Review Committees

Efforts aimed at strengthening the ethical review committees shall be promoted.

6.2 Education and Training

6.2.1 Special education for people with disabilities

A number of communication strategies have been used in the country to create awareness about HIV/AIDS in Malawian
communities. Unfortunately, some of these strategies are not accessible to people with disabilities, more especially those who have hearing impairments and those who are visually impaired. Institutions which provide special education and training to people with such disabilities should be strengthened including the embodying of HIV/AIDS research and training issues into the curriculum.

6.2.3 Grant Proposal Writing

There is lack of capacity even amongst senior researchers in the country on how to write research proposals which can compete at the global level for grants. There is need to identify senior researchers who can be trained in research proposal development. The National Aids Commission shall aim at developing a group of trainers in research proposal development who will in turn provide local training in proposal development.

6.2.4 Training in Appropriate Areas

The limited number of laboratory technicians that Malawi has especially with reference to carrying out laboratory work as a response to HIV/AIDS, necessitates the training of more technicians in areas such as blood screening, techniques, perfection and data recording on consumption and output. Similarly, there is need for training for stakeholders in such areas as HIV/AIDS research design, methodology, (bio)ethics and other relevant areas. Training for people working in pharmaceutical institutions both in public and private sectors should be emphasized especially for the quality of ARVs and other drugs.
6.2.5 Vaccines and Immunology

Although Malawi is at present not directly involved in vaccine development work for HIV/AIDS prevention, there is need to orient local health personnel on vaccine research activities including immunology.

6.2.6 Undertake Study Tours and Exchange Visits

A combination of formal and informal training provides a multiplicity of benefits. Undertaking tours to and exchange visits with Ethics Committees and HIV/AIDS research institutions within and outside Malawi shall promote the transfer and acquisition of appropriate skills.

6.2.7 Behaviour Change Communication

In order to ensure effective behaviour change communication (BCC), media institutions need training in developing evidence-based behaviour change communication strategies.

7.0 HIV/AIDS RESEARCH PRACTICE AND ETHICS

Regardless of the reasons for conducting any research, the welfare of research subjects is fundamental to the credibility of its findings. Rights of research subjects have to be respected during the conduct of any research. Protection of human subjects during the conduct of research should, therefore, be one of the researcher’s major concerns. It is the responsibility of researchers and funding agencies to ensure that all HIV/AIDS related studies adhere to international as well as national ethical guiding principles. The international guiding principles include those outlined in the Helsinki declaration of 1964 and its subsequent revisions, the CIOMS International ethical
guidelines for biomedical research involving human subjects and the operational guidelines for ethical committees that review biomedical research as provided by WHO.

In light of the foregoing it is very pertinent that each research proposal on HIV/AIDS be subjected to review by professional ethics review boards existing in the country. This will help in protecting and upholding the credibility of our valued researchers working on HIV/AIDS in Malawi as well as protecting research subjects from possible abuse. Researchers therefore need to get approvals on each research work before they start data collection. In Malawi health related research proposals are reviewed and approved by the National Health Sciences Research Committee and the College of Medicine Research and Ethics Committee. The College of Medicine Research Committee reviews research proposals submitted by faculty members and students of the College of Medicine and Kamuzu College of Nursing while the National Health Sciences Research Committee reviews proposals of national interest.

Proper HIV/AIDS Research Practice and Ethics constitute a sound HIV/AIDS research governance that is essential to ensure not only quality of HIV/AIDS research in order to achieve competitiveness and relevance but also to carry out research in a manner that the public can have confidence in and benefit from. To achieve this, the strategy calls for the adherence of stakeholders to the following HIV/AIDS research practices that are in line with the requirements of the National Health Sciences Research Committee and the College of Medicine Research and Ethics Committee.

7.1 Call for Research Proposals

The National Aids Commission shall call for research proposals from the public in the priority areas through any appropriate media. The commission shall only support research projects that address
priority areas and meet the requirements of the local ethics review committees. In calling for research proposals, the Commission shall

7.1.1 Publicise priority research areas for the knowledge of the public

7.1.2 Draw the attention of researchers to prepare their proposals for funding according to the NAC grant facility guidelines

7.1.3 Indicate proposal submission deadline

7.2 Research Proposal Format

Notwithstanding 7.1.2, researchers shall also be required to prepare research proposals in the format required by either the National Health Sciences Research Committee or the College of Medicine Research and Ethics Committee in readiness for submission for scientific and ethical review.

7.3 Proposal Review Meetings

The researchers shall ensure that their proposals have been scientifically and ethically reviewed by the appropriate committees as indicated in section 7.2 above. Depending on the case, a proposal may be subjected to an expedited review by any of the designated committees.

7.4 Amendments to Approved Research Proposals

All researchers shall be expected to stick to the approved research protocols. Any alterations to the approved protocol shall be given fresh considerations by either the National Health Sciences Research Committee or College of Medicine Research and Ethics Committee for ethical clearance, and the National AIDS Commission for funding consideration if it was initially funded by the commission.
7.5 Ethical Considerations

Generally, the proposed HIV/AIDS research shall have to take into consideration ethical principles of respect and justice to, and beneficence for the research participants and the society/community. To ensure this, researchers shall develop their proposals with respect to the following ethical practices;

7.5.1 Informed Consent

Under this,

7.5.1.1 A full description of the process for obtaining voluntary informed consent for participants including the identification of those responsible for obtaining consent shall be indicated by all researchers

7.5.1.2 The adequacy, completeness and understandability of written and oral information to be given to the research participants shall have to be made

7.5.1.3 The provisions for receiving and responding to any queries and complaints from research participants or their representatives during the course of a research project shall need to be indicated

7.5.1.4 Avoid undue inducements (e.g. money, gifts)

7.5.2 Protection of Research Participant Confidentiality

Under this, the researcher

7.5.2.1 Shall make a description of the persons who will have access to personal data of the research participants, including medical records and biological samples
7.5.2.2 Shall make a description of the measures to be taken to ensure the confidentiality and security of personal information concerning research participants

7.5.2.3 All the HIV/AIDS research studies that have not been tendered by NAC shall also be reviewed as per above ethical practices and guidelines of the National Health Sciences Research Committee or College of Medicine Research and Ethics Committee.

8.0 MONITORING AND EVALUATION (M&E) OF HIV/AIDS RESEARCH

The following tools shall be used in the monitoring and evaluation of HIV/AIDS research projects;

8.1 Technical Progress Report

Submission of technical progress reports shall depend on the lifespan of the research projects. The period for the maximum of one year shall be deemed short term while the period more than one year up to four years shall be deemed medium term. Beyond four years shall be long term. The Principal Investigator and his/her Collaborators shall submit to the National Aids Commission (NAC) and the National Research Council of Malawi (NRCM) at least two progress reports (for short term projects); at least four reports (for medium term projects); and at least six reports (for long term projects). This is a must for all research projects/studies being conducted in Malawi irrespective of the source of finances for those projects.

8.2 Final Report

The Principal Investigator and his/her Collaborators shall at the end of the project submit two copies of a well-bound final report and an
electronic version of the same to NAC and NRCM. Before submitting the final report to NAC and NRCM, the researcher shall have sought review and approval from the designate committees mentioned in section seven.

8.3 Field Visits

A schedule of field visits shall be drawn up by NAC. Field visits shall be done at least once for short-term projects, at least four times for medium term projects and at least five times for long-term projects. The visits will be conducted by any competent persons/institutions appointed by the NAC. The visiting team shall submit a report to NAC of any project that has been visited and evaluated. Depending on the nature of the report, NAC may submit these reports to either NHSRC or COMREC for discussion. The copies of the same shall also be sent to NRCM for monitoring purposes. Depending on the comments that may be made by the NHSRC or COMREC, NAC shall give a feedback to the researcher with a copy of the same to the NRCM. Any reasons for suspension or termination of the research project by either NHSRC or COMREC shall be fully communicated to the researcher and the NRCM.

8.4 Documentation and Dissemination of HIV/AIDS Research Results

The dissemination of research results is part and parcel of the research system. To ensure that this is achieved, the following will be done:-

8.4.1 NAC shall annually facilitate the organization of HIV/AIDS research results dissemination conferences that shall be undertaken by the National Research Council of Malawi.

8.4.2 Each institution carrying out HIV/AIDS research shall form
a committee on research results dissemination. The main task for this committee would be to ensure that research results reach end-users and other stakeholders including communities that participated in research.

8.4.3 Any researcher/institution shall establish a specific budget line on dissemination of research results.

8.4.4 Institutions shall produce annual reports that will show organisations’ set-up, performance, available resources, summaries of HIV/AIDS research programmes and activities, and results of research projects undertaken during the year.

8.4.5 Institutions shall produce occasional papers including HIV/AIDS research bulletins and circulars, and popular publications with results presented in a simplified form for public consumption after a researcher shall have sought review and approval from the designated review committees.

8.4.6 Institutions shall be encouraged to take advantage of the electronic and print media for HIV/AIDS research features and interviews/discussions in HIV/AIDS.

8.4.7 Institutions shall encourage and support researchers to publish results in local and international journals after approval by NHSRC or COMREC.

8.4.8 Researchers/institutions shall properly package and exhibit results at various fora to make them available to various stakeholders.

8.4.9 Institutions shall develop databases and compile annual directories of HIV/AIDS research projects.
8.4.10 The National Research Council of Malawi shall create and develop a national database for HIV/AIDS research done.

8.4.11 The National Research Council of Malawi shall create a website for mounting HIV/AIDS Research findings.

9.0 FINANCING ARRANGEMENTS FOR HIV/AIDS RESEARCH

The sourcing of funds for priority HIV/AIDS research shall be the responsibility of the researcher. Finances for the HIV/AIDS research shall be sourced from within and/or outside the country.

9.1 Financing Arrangements for NAC Funded Research

The NAC shall provide research grants in the identified priority areas basing on the guidelines as stipulated below;

9.1.1 Researchers shall prepare proposals for funding from NAC according to the guidelines as provided by NAC.

9.1.2 For purposes of accountability, the researcher applying for any research grant from NAC shall have already been affiliated to an institution as provided for in the National Research Council of Malawi publication of science and technology institutions directory. Such researchers shall negotiate affiliating arrangements on their own.

9.1.3 The institution to which the researcher is affiliated shall be the guarantor of the research funds. Funds sourced through NAC shall be disbursed only when the affiliating institution has indicated the guarantorship. To this effect, a contractual agreement between NAC, the researcher and the affiliating institution shall be signed before the disbursement of any funds.
9.1.4 NAC shall disburse grant for only the ethically and scientifically approved research protocols

9.1.5 Research funds sourced shall be deposited into the bank account of the researcher’s affiliating institution and not into the individual’s bank account.

9.1.6 The NAC shall reserve the right to audit books of accounts of the disbursed research grant

9.1.7 Researchers shall conform to the research grant guidelines as stipulated in the NAC grant facility

9.1.8 Financial report shall be written and submitted to NAC at the end of the study period.

9.1.9 **Financing Arrangements for Research Funded through Other Sources**

Under this, researchers shall be obliged by the financial procedures, guidelines and regulations of an identified donor.