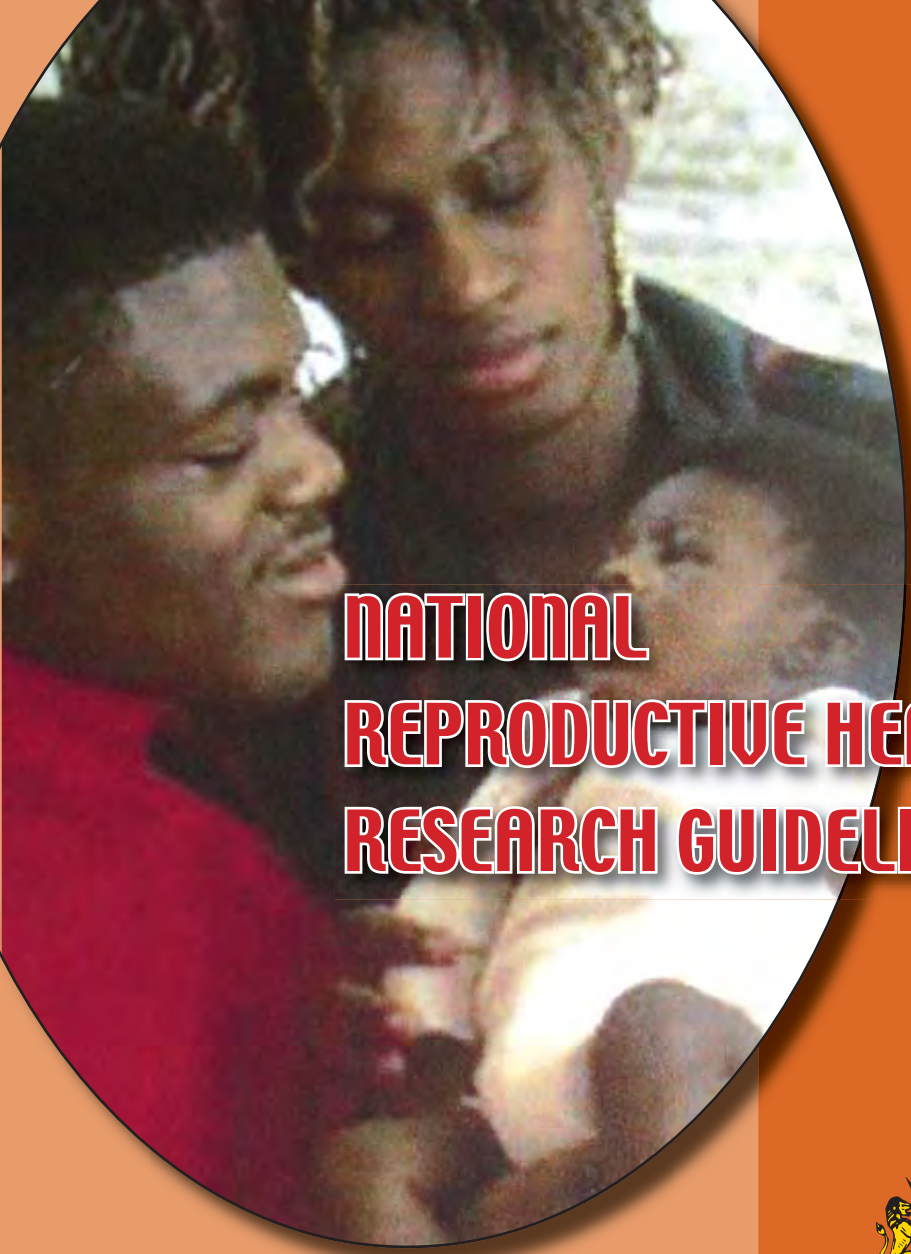

NATIONAL REPRODUCTIVE HEALTH RESEARCH GUIDELINES

Republic of Kenya

Ministry of Health
Division of
Reproductive Health

NATIONAL REPRODUCTIVE HEALTH RESEARCH GUIDELINES

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Foreword

The Division of Reproductive Health (DRH) within the MOH is responsible for planning, implementing, and monitoring reproductive health programs in the country. The DRH is guided by the National Reproductive Health Strategy, which is a response to the Programs of Action of the 1994 United Nations International Conference on Population and Development (ICPD). The goal of the DRH is the "Provision of a comprehensive and integrated system of reproductive health care that offers a full range of services by the government, NGOs and the private sector, as outlined in the National Population Policy for Sustainable Development and the Kenya Health Policy Framework of 1994."

The National Reproductive Health Strategy is the framework for implementing a comprehensive reproductive health program. The Strategy is a gender-sensitive tool designed to assist policy, decision-makers, program implementers, researchers, and development partners direct the focus of their work, assess priorities, meet needs, and fill the gaps identified in the current reproductive health (RH) programs.

Currently, the DRH is focusing on safe motherhood and child survival, adolescent reproductive health, gender and reproductive health rights, family planning, STIs including RTIs, HIV/AIDS, community reproductive health, and monitoring and evaluation programs. The other areas reflected in the RH strategy, including infertility and RH tract cancers, are addressed within these six programs. Any person who wants to conduct RH research in Kenya is expected to utilize these guidelines in an effort to answer research gaps in these areas.

The DRH has identified research implementation as a key area for improving RH service provision. The DRH is addressing this need by producing these "Reproductive Health Research Guidelines" with technical assistance from researchers in reproductive health,

policy-makers and program implementers. The research guidelines address the focus RH research areas in Kenya, how RH research is to be conducted in Kenya, ethical considerations in RH research, and how utilization of the research findings should benefit programs and communities.

Using these guidelines, the DRH will take the central role in coordinating RH research and activities in the country. To this end, this document provides several recommendations on the role of DRH as the central coordinator and a step-by-step guideline on how to collaborate with the DRH on RH research.

The DRH calls upon researchers and other stakeholders in RH to ensure adherence to the guidelines in order to ensure quality RH research results, to avoid duplication of RH research in the country, and to ensure utilization of the research findings in programs and service delivery. The MOH through the DRH will continue to provide the necessary enabling environment and collaboration that enhances provision of quality reproductive health in the country.

Dr. Josephine Kibaru
Head, Division of Reproductive Health,
Ministry of Health

Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARH	Adolescent Reproductive Health
ARH&D	Adolescent Reproductive Health and Development
CBS	Central Bureau of Statistics
CIOMS	Council for International Organizations of Medical Sciences
DFID	Department for International Development
DRH	Division of Reproductive Health
EBP	Evidence-Based Practice
ECP	Emergency Contraceptive Pill
EOC	Emergency Obstetrical Care
FHI	Family Health International
FHOK	Family Health Options Kenya
FGC	Female Genital Cutting
FP	Family Planning
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GTZ	Gesellschaft Fur Technical Zusammen Aribeit, Germany
HIV	Human Immunodeficiency Virus
IBP	Implementing Best Practices
ICPD	International Conference on Population and Development
IEC	Information, Education, and Communication
IUCD	Intrauterine Contraceptive Device

JHPIEGO	John Hopkins Program for Reproductive Health
JICA	Japan International Cooperation Agency
JSI	John Snow International
KDHS	Kenya Demographic and Health Survey
KQM	Kenya Quality Management
KSPA	Kenya Service Provision Assessment
MCH	Maternal and Child Health
M&E	Monitoring and Evaluation
MDGs	Millennium Development Goals
MOH	Ministry of Health
NASCOP	National Aids & STD Control Program
NCAPD	National Co-ordinating Agency for Population and Development
NGO	Non-governmental Organization
PATH	Program for Appropriate Technology in Health
PEP	Post-Exposure Prophylaxis
PMTCT	Prevention of Mother-to-Child Transmission
PSI	Population Services International
RH	Reproductive Health
RHRU	Reproductive Health Research Unit
SDP	Service Delivery Point
STIs	Sexually Transmitted Infections
VCT	Voluntary Counseling and Testing
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WMA	World Medical Association
TBA	Traditional Birth Attendant

SECTION I

Overview of Reproductive Health in Kenya

:: Introduction

This document addresses guidelines for reproductive health (RH) research based on the Division of Reproductive Health (DRH) focus areas. Section One provides a background to general RH principles. The focus reproductive health research areas are presented in Section Two, and the process of implementing research with the DRH is discussed in Section Three. Section Four outlines basics on research ethics with an additional section on the National Council for Science and Technology regulations on clearance and implementation of any research conducted in Kenya.

The DRH seeks to improve its coordination of the multitude of reproductive health research and programmatic activities taking place in the country. This role will include review of all RH concept papers to determine whether they meet the current RH research priorities and the provision of guidance to potential researchers. Recommendations for the DRH's coordinating role, as identified in the 2004 DRH Consultative Meeting on the RH Research Agenda held between the DRH and partners in RH service provision, include:

- Forging partnerships between the DRH and local institutions such as universities and communities in order to increase local interest in RH issues. Proposed ways may include:
  - Developing collaborative RH proposals
  - Building research capacity

  - Creating forums for dissemination and utilization of the findings

- Developing national/international dissemination and utilization plans for RH information.
- Developing a checklist to guide researchers on how to collaborate with the DRH.
- Developing standards and rules for potential researchers interested in accessing RH data.

The DRH is not obligated to participate in the research activity. It is also not a requirement that the DRH participates as co-principal investigators in the research or as co-authors in any of the publications that emerge from the research activity. However, the researcher is obligated to submit a concept paper, a final report, and an abstract to the DRH for the research activity. This "tracking" mechanism will assist the DRH to keep an up-to-date account of RH research findings and the RH research activities taking place in the country. It also enables anyone seeking to work on research in Kenya to identify gaps, useful information, and potential collaborators. In its commitment to provide improved reproductive health services, the DRH has increased its efforts to establish mechanisms for coordinating and conducting priority research and utilizing research results. As demonstrated in the DRH Consultative Meeting on the RH Research Agenda in June 2004, it was agreed that:

- RH program decisions should be based on solid research findings.
- A national research agenda should be developed to ensure that relevant knowledge gaps are being addressed.

Although substantial RH research in Kenya has been conducted, the DRH has been unable to keep track of what has been done and who is doing what. They have also been unable to monitor the current knowledge gaps. The DRH developed a Reproductive Health Research Agenda that identifies the most critical areas (see Appendix 1 for the Executive Summary Section of the report). The full report is

available and can be downloaded at http://www.drh.go.ke/html/guidelines_res.asp or at the DRH resource centre. These focus research areas include:

- Safe motherhood and child survival
- Adolescent reproductive health
- Gender and reproductive health rights
- Family planning, and management of RTIs (including STIs)/HIV/AIDS[1]
- Community reproductive health
- Infertility
- Chronic illnesses and cancers of the reproductive system

In addition to established priorities, a coordinated approach to conducting, storing, and accessing RH research in the country is needed.

This undertaking is part of an ongoing initiative by the DRH and Family Health International (FHI) through funding by USAID to enhance research capabilities within the DRH. Researchers should ensure use of RH research results by program implementers and policy makers. They should appreciate the need to not only share the knowledge acquired through research but also ensure that the quality of the information is accurate enough to warrant utilization. Thus, prospective researchers will clearly outline the anticipated process of utilization of their RH research findings and their contribution to the overall RH program in Kenya. In the process of identifying potential users, it is important to indicate appropriate communication tools for dissemination and utilization.

[1]The Division of Reproductive Health emphasis is on studies related to PMTCT. Other HIV/AIDS research is commonly conducted under the auspices of National AIDS & STD Control Program (NASCOP).

:: Reproductive Health in Kenya

Reproductive health is defined as "a state of complete physical, mental, emotional and social well-being and not merely absence of disease or infirmity, in all matters relating to the reproductive health system and to its functions and processes" (ICPD 1994). In Kenya, modern methods of contraception were available to the population through the MOH health facilities and private/NGO sector as early as 1957. However, it was not until independence and after the 1962 census that it was revealed that population growth was as high as 3 percent and that the population would double in the next two decades, that the Government of Kenya recognized the importance of family planning. In Sessional Paper No. 10 of 1965, the Government of Kenya recognized the importance of population planning for sustained socio-economic development.

In 1967, the National Family Planning Program was launched, making Kenya the first sub-Saharan African country to have such a program. This was followed by a more focused integrated program of Maternal and Child Health and Family Planning (MCH/FP). However, despite all efforts, the family planning program did not accelerate as expected given the targets set in the 1974-79 National Development Plan. Thus, the first two decades after independence were characterized by rapid population growth as a result of increasing fertility rates and declining mortality rates. This resulted in one of the most rapidly increasing populations in the world with an accelerated growth rate of 3.8 percent per year and a total fertility rate (TFR) of 8 children per woman in the early 1980s.

While the TFR has been declining, it has stalled in recent years at around 5 children per woman according to the 1998 and 2003 Kenyan Demographic Health Surveys (KDHS). According to the 2003 KDHS, the overall TFR for Kenya is 4.9 children per woman, but is 3.3 in urban areas and 5.4 in rural areas. Approximately 82 percent of the population lives in rural areas, where contraceptive prevalence estimates are also the lowest. The percentage of currently married women using modern contraception was 27 percent according to the

1993 KDHS, but has stabilized at 32 percent in both the 1998 and 2003 KDHS (CBS, 1999, 2004).

Preliminary results of the 2004 Kenya Service Provision Assessment (KSPA) reveal that many youth in need of sexual and reproductive health care do not access the existing services because providers are often biased, unfriendly, or not adequately trained to serve sexually active youth. The proportion of facilities with youth-friendly services was found to be only 12 percent, (NCAPD, 2004).

Despite major efforts in the provision of adequate RH services, success still remains elusive in Kenya. Although there are approximately 4,020 health facilities in the country, not all of them currently offer comprehensive reproductive health care. Furthermore, the 4,020 health facilities designated as service delivery points (SDPs) for family planning provision are not equitably distributed throughout the country. Making services accessible is therefore an immediate concern of the government, non-governmental organizations (NGOs), and the private sector. Consideration of geographical and cultural diversities and socio-economic as well and gender disparities must be made.

Although significant gains have been achieved in Kenya's health indicators, high maternal morbidity and mortality levels still persist, particularly as associated with prolonged and obstructed labor, unsafe abortion, hemorrhage, hypertensive diseases of pregnancy, sepsis, anemia, malaria, STDs and HIV/AIDS (Central Bureau of Statistics (CBS) 2004). In fact, the findings of the most recent 2003 KDHS show an upsurge of fertility and childhood mortality with diverse regional disparities (CBS 2004). According to the 2003 KDHS, about 414 women per 100,000 live births die from pregnancy-related mortality and morbidity including unsafe abortions. An important question for research remains as to why the majority of women continue delivering at home without the assistance of medically trained personnel.

:: Specific Objectives of the RH Research Guidelines

The RH Research Guidelines will:

- Enhance the ability of DRH in research management, documentation, and coordination, and minimise duplication of research efforts.
- Provide clear steps for RH researchers to collaborate with the DRH.
- Facilitate an increase in feedback of research findings to beneficiaries and in utilisation of research findings to address health problems.
- Facilitate an increased demand for research findings through advocacy and dissemination to policymakers and program implementers.
- Enhance proper conduct of RH research using scientific principles.
- Advance the application of research ethics to protect human subjects.

:: Target Audience for the RH Research Guidelines

The guidelines were developed to be used primarily by RH researchers wishing to conduct RH research in Kenya (including biomedical, clinical, and operations research). Policy-makers, practitioners, and donors will also benefit from understanding the new research coordination mechanisms and requirements in place for the DRH and RH researchers. The DRH staff will use the guidelines to assess submitted research proposals and to ensure that the proposed research benefits the country and maintains required ethical standards. It is not essential for the researcher to collaborate with the DRH but

it is essential for him/her to inform the DRH of the ongoing work and submit a final report and abstract for the country's RH research database.

:: How to Use the RH Research Guidelines

These guidelines should be used to:

- Check and confirm if, or which of, the established reproductive health priorities are being addressed by proposed research.
- Assess a research proposal for consistency with acceptable practices and standards outlined in the guidelines.
- Ensure the laboratory or clinical research conforms to the six practices outlined under Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and the ethical principles as adopted by the World Medical Association (WMA) in Helsinki in 1964.
- Assess conformity to ethical standards emphasised under the ethical section of the guide.
- Provide a basis for reviewing the concept proposals presented to the DRH.
- Facilitate a tracking mechanism for recording all RH research being conducted in the country.
- Ensure adequate dissemination and utilization of RH research findings by adhering to the DRH checklist.
- Provide a standard for supervision of any RH research activity being undertaken in the country.

These guidelines outline how researchers can conduct research in Kenya. Any researcher wishing to conduct RH research in Kenya (including biomedical, clinical, and operations research) in collaboration with the DRH should follow the steps in Section 3 and as illustrated in the flowchart (Figure 1).

Researchers should also consult and follow the National Council for Science and Technology Guidelines that appear in Section 4.

SECTION II

2004 DRH Focus Research Areas

:: Background

The MOH held a workshop in June 2004 in Nairobi, Kenya, followed by a series of interviews with practitioners and experts in the RH field. The purpose of the workshop and the subsequent interviews was to learn, from those most actively involved, what are the gaps in reproductive health programs and how research can be used to address those gaps. The research topics identified by the participants of this workshop are seen as an important step in fulfilling the government's promise of reproductive health for all of its citizens.

Several research priorities were identified for each topic area at the June 2004 consultative meeting by the DRH and partners, as documented in "The Reproductive Health Research Agenda Setting in Kenya." During this meeting, focus RH research areas were identified based on the eight components of reproductive health. Based on this, the focus areas are still evolving, and therefore, these guidelines will eventually need to be updated from time to time. The following is a summary of recommendations by topic area.

:: Research Priorities

Safe Motherhood and Child Survival

Due to high maternal mortality and evidence of increased childhood mortality in Kenya, the DRH and collaborative partners have

developed several guidelines in the area of safe motherhood. These include "Standards for Maternal Care in Kenya" (DRH et al. 2003), a background manual to the Safe Motherhood Know-How project; "Clinical Audit for Effective Delivery of Maternal Care in Kenya." an institutional manual on carrying out clinical audits and evidence based practices (EBP) and continuing medical education.

Some research gaps that need to be addressed include:

- Determining how to measure the effectiveness of current maternal health programs.
- Determining program and intervention effects on reducing maternal mortality.
- Determining effects of knowledge, attitudes, and practices on pregnancy and its complications during pregnancy and delivery.

Other considerations for safe motherhood according to the "Standards for Maternal Care in Kenya" manual (DRH et al. 2002) include the need for researchers to pay special attention to the management of hemorrhage, infections and sepsis, prolonged and obstructed labor, pre-eclampsia, and abortion.

Adolescent Reproductive Health

Future research on adolescent reproductive health needs to:

- Define adolescent/youth reproductive health consistent with the Adolescent Reproductive Health and Development (ARH&D) Policy guidelines to streamline research work in the area (See ARH&D Policy Guidelines 2004).
- Explore the epidemiology of adolescent problems and studies on adolescent health and welfare information.
- Address HIV/AIDS and how to prevent and treat the disease using interventions, peer counseling, and teacher and mentor guidance.

- Evaluate other programs meant to reach and teach young audiences taking into account the multi-cultural aspects of the Kenyan society.

Gender and Reproductive Health Rights

Important gender research questions that were identified included:

- Policy compliance to gender considerations in Kenya.
- Extent to which the existing policies and practices protect reproductive health rights.
- Extent to which the government adheres to international conventions and declarations.
- Gender issues among RH providers and client-provider interactions.
- Variation of gender issues by age, social and economic status, ethnicity, religious affiliation, and other social characteristics.
- Relations between and among men and women including differences in status, power and roles, vulnerability, access to resources, physical traits, and family relations.
- Recognition that relations between women and men often change over time and can differ according to women's and men's life-cycle stages (e.g., in some societies, older women are accorded higher status than younger women). Also, that relationship can vary by situation and activity (e.g., women may have power to make certain kinds of decisions but not others).
- Involvement of women and men not only as respondents but whenever possible, in study design, implementation, and interpretation of results. Involving women's (or men's) health advocates can be especially helpful in making sure the research is relevant and sensitive to people's experiences.

Family Planning, STIs, and HIV/AIDS

In 2004, the DRH and partners noted that contraceptive security is the greatest challenge to family planning and its linkage to a reduction in fertility. Also, several challenges relating to HIV/AIDS and STIs including reducing transmission, prolonging lives through drug therapy, treatment of opportunistic infections, and many others were noted. Some of the immediate research agenda questions include:

- The effect of knowledge, attitudes, and practices on contraception.
- The effect of the status of contraception security, procurement, and logistics.
- The urgent need to determine the factors contributing to the evident trend in the rise of fertility from a total fertility rate of 4.7 in 1998 to a rate of 4.9 in 2003.

Community Reproductive Health

Kenya is a country with diverse cultural practices and attitudes. Continuing research needs concerning community RH include:

- Identifying contextual differences and/or level of support for communities' RH needs.
- Determining the level of community education on:
  - the benefits of health facilities
  - disadvantages for mothers delivering without skilled attendance
  - women and traditional birth attendants' (TBAs) awareness of the signs and symptoms of maternal care risks during pregnancy and at delivery
  - the importance of a community emergency transport system
  - adolescent and youth RH needs
  - disadvantages of early marriage and regressive cultural practices

- Determining the quality and quantity of information, education, and communication (IEC) materials on community RH responsibility at the community-level to increase awareness.
- Identifying community resources and willingness of communities to contribute (even in kind) to the enhancement of their community's RH.
- Investigating the role of the community in overcoming discrimination and stigma related to HIV and AIDS and other RH related issues.
- Examining the community policy compliance to gender considerations and other RH issues.
- Exploring the level of knowledge and awareness about dual protection methods.
- Investigating community and cultural barriers to FP methods especially male and female condoms.
- Carrying out more community studies on the willingness to increase male involvement in RH.
- Ensuring that women and communities know the dangers of induced abortions. Are they able to identify complications of abortion and access existing post-abortion care (PAC) services promptly?

Infertility

Infertility, which has multiple causes and consequences, is a global public health concern. About 10 percent of all couples worldwide are or have been infertile. Because family planning professionals devote much of their careers to helping clients avoid unintended pregnancies, they may neglect the issue of unintended infertility. But efforts to better prevent, diagnose, and treat the main causes of unintended infertility could help preserve the fertility of millions worldwide. Key points requiring our focus in this area are that:

- Infertility often involves both members of the couple.
- Sexually transmitted infections (STIs) are the primary preventable causes of infertility.
- Chlamydial infection and gonorrhea are the two STIs most clearly associated with infertility.
- Screening can identify these two often-silent STIs.
- Postpartum and postabortion infections are also associated with infertility; and.
- Contraceptive use does not cause infertility.

Although infertility is considered by some to be primarily a woman's problem, men often contribute to and are also affected by it. Thus, we need to explore how infertility affects men, the ways in which men can protect themselves and their partners from STIs, and how reproductive health programs and clinics can help men understand and prevent infertility.

Infertility management is an important component of reproductive health services. When infertility occurs, couples should not be denied treatment, including assisted reproductive technologies. One of the best-known and most common technologies is *in vitro fertilization* (IVF), a procedure in which a man's sperm and a woman's egg are fertilized in a laboratory and the resulting embryo is transferred into the woman's uterus.

Other technologies include intracytoplasmic sperm injection (ICSI), in which a single sperm is injected into a single egg during IVF, and gamete intrafallopian transfer, an alternative to IVF in which sperm and unfertilized eggs are surgically placed in a woman's fallopian tubes. Global demand for such help is undeniable. But some experts are concerned about the cost and difficulty of providing such interventions in the developing world. Nonetheless, an example from Kenya demonstrated that assisted reproductive technologies are feasible and successful in low-resource settings where staff are trained and equipment is available. In Mombasa, an IVF center was created in

1995, and nearly 50 patients had attended by early 2003, according to Dr. Abdallah Kibwana, an obstetrician/gynecologist from Mombasa's Coast General Hospital. At a regional obstetrical and gynecological conference, he reported that 19 of the patients seen at the IVF center have conceived with the help of simple ovarian stimulation, and two babies have been born using IVF. Further research in this area will provide hope for couples who want to have children despite their physiological challenges. There is need to incorporate assisted RH technology appropriately. (Network, 2003, Kibwana, 2003).

Chronic Illnesses and Cancers of the Reproductive System

Reproductive health cancers contribute to the burden of malignancies and cancer of the cervix ranks as the number one cancer in Kenya. Currently in Kenya, there is no adequate mapping of the extent of cancers in women. Organized cancer prevention programs are in their infancy stages and have not been adequately implemented.

- It is suggested that screening for cervical cancer in the VCT should be a part of a thorough integration of services.
- HIV+ women are more prone to these cancers and therefore should undergo regular check-ups.

However, existing staff lack specialized skills for cancer management. There is a shortage of staff, inadequate equipment and supplies, lack of awareness, and no available screening or culture tests. Treatment that is available is expensive and limited to very few facilities. There is also a problem of late diagnosis. The predisposing factors of HIV/AIDS and cervical cancer are nearly identical, and even young women are at risk. Creating demand awareness is a challenge to the Ministry of Health and should be integrated nationally with other services, such as antenatal care, to give the best training to clinicians and nurses.

Questions raised revolve around policies, programs, community awareness and empowering the health worker to provide care and support.

The specific questions research could address are:

- How do we raise awareness in the community and among women of the need for and the availability of screening for gynecological cancers?
- How do we address the difference in cost between early and late diagnosis of all RH cancers?
- How do we increase the proportion of care providers able to provide cancer screening, as well as manage services at all levels of health care?
- How do we improve policies and systems for terminal care?
- How do we integrate prevention and early detection into ongoing programs such as VCT?
- What is the link between reproductive health cancers and HIV/AIDS?

SECTION III

Implementing Reproductive Health Research with the DRH

:: Introduction

The DRH is the division within the Ministry of Health responsible for planning, implementing, and monitoring reproductive health programs in Kenya and is guided by the National Reproductive Health Strategy. The National Reproductive Health Strategy is the framework for implementing DRH's comprehensive reproductive health program. The Strategy is a gender sensitive tool designed to assist policy decision-makers, program implementers, researchers, and development partners to focus their work, assess priorities, meet needs, and fill the gaps identified in the current reproductive health programs.

As outlined in the National Population Policy for Sustainable Development and the Kenya Health Policy Framework of 1994, the goal of the DRH is the "Provision of a comprehensive and integrated system of reproductive health care that offers a full range of services by the government, NGOs and the private sector."

:: How to Collaborate with the DRH on Reproductive Health Research

Steps for the Researcher

The following steps outline the process for submitting proposals to the DRH:

STEP 1: Utilizing the current DRH Research Agenda (Appendix 1), identify which focus area your proposed research addresses. In case of any emerging research concern not outlined in the current research agenda, but identified by the Ministry of Health as a special need, the researcher is required to present an official request form to the MOH.

STEP 2: Submit a concept paper (two-page limit) and the DRH Research Submission Checklist (Appendix 2) to:

The Head, Division of Reproductive Health
PO Box 43319, NAIROBI, KENYA,
Tel: 254-20-2725105, Fax: 254-20-2716814
Email: drh-head@africaonline.co.ke

Guidelines for Concept Proposals

A standard concept proposal should not be more than two pages and must include the following sections:

- Background/potential for public health impact
- Basic study/subproject design and methods
- Study site(s)
- Study population
- Brief statement of study design and sample size selection

- Methods for data collection
- Expected outcomes
- Feasibility of conducting research
- Potential for scale-up and/or replication and utilization
- Ethical considerations
- Implementing/collaborating agency(s)

For every concept paper submitted to the DRH the researcher will be required to complete the submission checklist in Appendix 2. The required information on this form includes descriptions of the potential policy or programmatic implications of the study, the study design, the implementing agency, and the investigators names and qualifications.

STEP 3: The DRH will review the concept paper and submission checklist and establish the following:

- Institutional contact information
- The DRH focus area being addressed by the proposed research
- Proposed location of the activity
- Project description
- Expected outcomes
- Feasibility of conducting research
- Potential for scale-up and/or replication
- Implementing/collaborating agency(s)

STEP 4: The DRH makes a decision to collaborate or not based on focus issues, staff availability, and work-plan schedule.

STEP 5: The DRH informs the researcher of the decision on whether they will collaborate or not within four weeks of receipt of the request. If collaboration is possible, the DRH will sign off on the submitted research checklist. It is not mandatory for the DRH to collaborate on the research activity. Other agencies in Kenya such as the Kenya Medical Research Institute; the Department of Obstetricians and Gynecology, University of Nairobi; Moi Referral and Teaching Hospital; Aga Khan Teaching University Hospital can collaborate in RH research.

If collaboration is not possible, the DRH will communicate other possible timing options or other collaborators. **Even if the study proceeds with a different agency, the researcher is still obligated to fulfill Step 8 of the process (final report submission).**

STEP 6: Develop the full proposal and submit it to the relevant ethics review board for approval.

STEP 7: Implement and complete the research activity. If collaborating with the DRH, seek formal agreement with the DRH. The DRH will be involved in:

- Protocol meetings with provincial MOH staff to introduce the project and staff, and help facilitate local collaboration.
- Training data collectors and field monitoring visits.
- Data interpretation and national dissemination meetings.
- Final report review and utilization of findings.

All travel and accommodation costs for DRH staff should be included in the proposal costs by the researcher.

STEP 8: Submit final report and abstract to the Head, Division of Reproductive Health for inclusion in national RH research database.

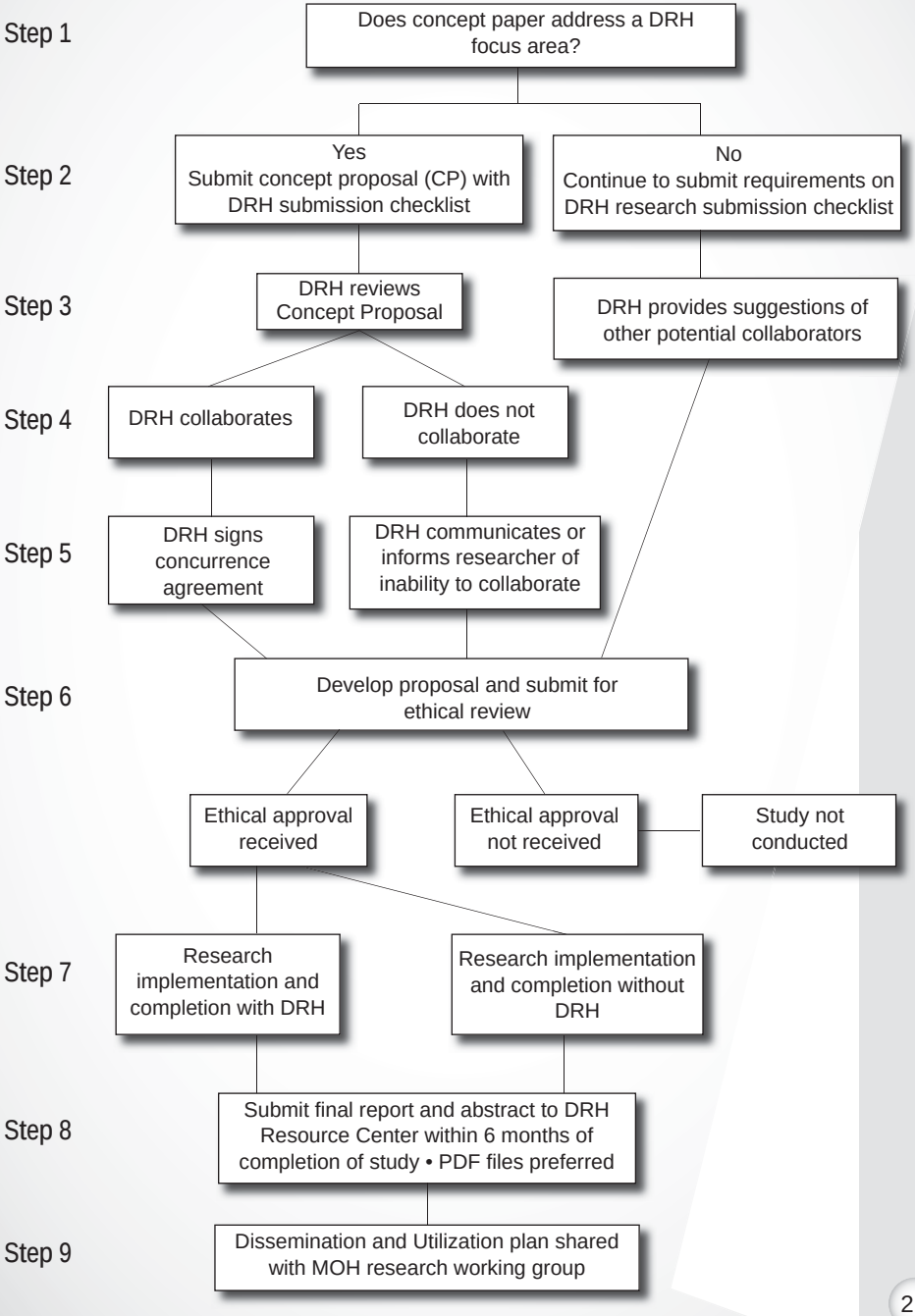
STEP 9: Disseminate the report so that findings can be utilized. The DRH will take responsibility to:

- Upload all abstracts and final reports onto the DRH website.
- Identify opportunities within the program to implement research findings.

The researcher will take responsibility to:

- Design a dissemination and utilization plan.
- Implement the dissemination and utilization plan (e.g., through dissemination workshops, final report, research briefs, policy briefs, and action plans).

Figure 1: DRH Process Flowchart

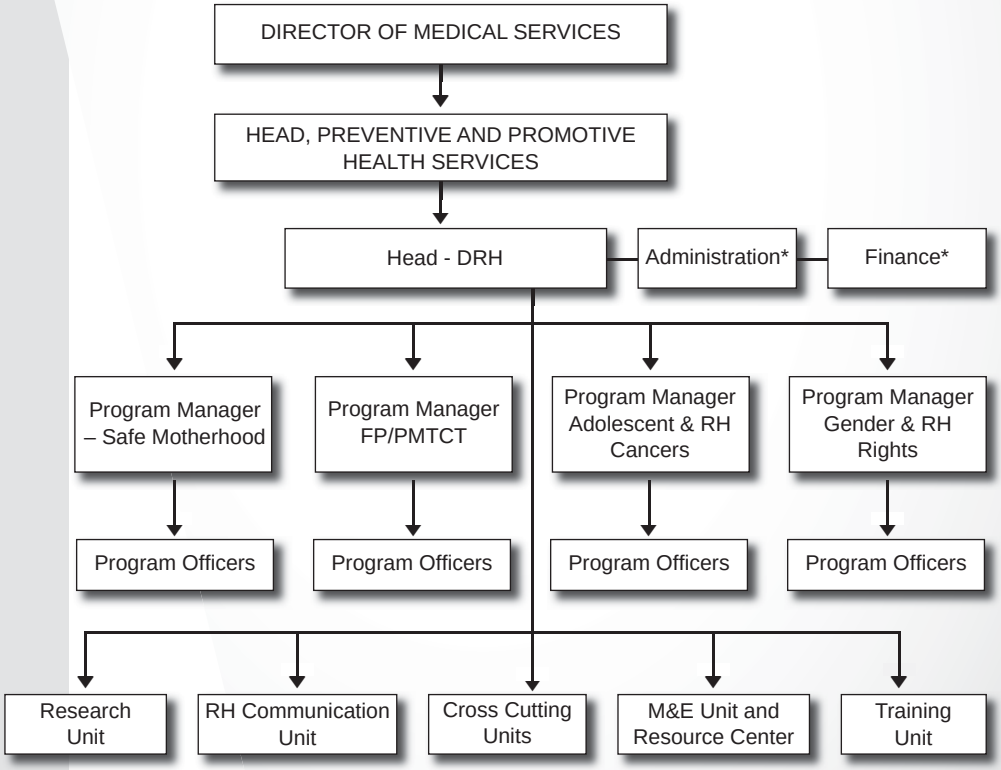


:: DRH Program Areas

As shown in Figure 2, the DRH program is structured to reflect four key program areas of RH focus; These four areas are:

1. Safe motherhood and child survival.
2. Adolescent reproductive health and RH cancers
3. Gender and RH rights.
4. Family planning and STIs, HIV / AIDS, PMTCT.

Figure 2: Structure of the Division of Reproductive Health



* Finance and Admin also serve the other divisions (Child Health, KEPI, Nutrition)

A program manager oversees implementation of each component and manages the corresponding research topic area. The other areas reflected in the RH strategy including infertility and RH tract cancers are addressed within these four programs. The following is a brief description of the DRH programs.

:: Safe Motherhood and Child Survival

The DRH, in partnership with numerous local and international partners, has implemented more than 20 projects across Kenya to address downward trends in safe motherhood and child survival. According to the 1998 and 2003 KDHS, the proportion of women seeking medical assistance during delivery declined from 50 percent to 42 percent, and infant mortality increased from 62 to 78 deaths per 1,000 live births. In collaboration with partners such as JICA, GTZ, USAID, JSI, AMKENI, DfID, Population Council, JHPIEGO, WHO, and many others, the DRH is working to improve maternal and child health by advocating for safe motherhood, building the capacity of health service delivery staff, and improving service delivery through provision of adequate supplies and equipment.

These interventions are based on the eight pillars of safe motherhood: family planning and pre-pregnancy care, focused antenatal care, prevention of mother-to-child transmission of HIV/AIDS, post-abortion care, clean and safe deliveries, essential obstetric care, essential neonatal care, and targeted postpartum care. In response to the identified need for standards of care, the DRH and partners developed a standards of care manual for obstetric emergencies including: hemorrhage, sepsis, pre-eclampsia and eclampsia, obstructed labor, and abortion. It also identified program gaps to which research can significantly contribute.

:: Adolescent Reproductive Health

Kenya's 2003 "Adolescent Reproductive Health and Development (ARH&D) Policy" is a multi-sectoral policy which aims to integrate adolescent sexual and reproductive health issues into mainstream health and development activities. The sexual and reproductive health of adolescents is a priority for Kenyans, not only because youth represent more than one-third of the population, but because they are the generation of the future. Unwanted, early pregnancies and infection with STIs, including HIV, are two of the most serious reproductive health outcomes of early and unprotected sex (Askew et al. 2004, Mensch et al. 1998).

After developing the ARH&D Policy, the DRH, implemented a program designed to:

- Improve adolescents' knowledge about reproductive health.
- Encourage a responsible and healthy attitude toward sexuality.
- Delay onset of sexual activity among younger adolescents.
- Decrease risky behaviors among adolescents who are already sexually active.
- Increase provision of youth-friendly services by trained service providers and peer educators.

The ARH program is currently being implemented through the DRH in five provinces with partners including UNFPA, UNICEF, WHO, Population Council, PATH and Save the Children.

:: Gender Considerations and Reproductive Health Rights

In Kenya, although women make up about 52 percent of the total population and account for over 70 percent of all food production, their contribution to social and economic development is often not

recognized. Gender disparities in literacy, educational attainment, and economic achievement are evident. The 1999 census revealed that the literacy levels for males aged 10 and higher stood at 78 percent compared to 70 percent for females in the same age category. Due to low educational attainment and retrogressive socio-cultural practices, women in Kenya are characterized by low participation in decision-making.

The Kenyan government's Gender and Reproductive Health Rights Program, implemented by the DRH with other local and international partners, aims to:

- Remove legislation, policies, and traditional or cultural practices that discriminate against women and girls.
- Promote and provide comprehensive reproductive health services for women.
- Achieve equality and equity between men and women.
- Ensure that women have access to information, education, and services needed for them to achieve good sexual health and to exercise their reproductive rights and responsibilities.

The gender initiative's first collaborative efforts were with Liverpool VCT and Care-Kenya to develop and launch National Guidelines for the Medical Management of Rape and Sexual Violence and with GTZ to develop a plan of action against female genital cutting. Future efforts will include scale-up of services for victims of rape and other sexual violence, and a project to integrate gender issues into HIV/AIDS policies and services. Several guidelines and considerations are provided in the "National Guidelines: Medical Management of Rape/Sexual Violence 2004," and are important for researchers' consideration. These guidelines are available online from the DRH website www.drh.go.ke and at the DRH Resource Centre.

:: Family Planning, PMTCT, STIs, and HIV/AIDS Program

The 2003 KDHS revealed that the modern contraceptive prevalence rate has stalled at 32 percent among married women with major variations nationally. The unmet need for contraception is 24 percent among married women (CBS 2004). Out of the total unmet need for family planning, 14 percent is related to birth spacing and 10 percent to limiting children. The KDHS also revealed that about 38 percent of women discontinue use of FP methods within 12 months of adopting a method, up from 33 percent in 1998.

The Family Planning, STIs, and HIV/AIDS program was officially set up in the DRH in early 2003. The main objectives of the program are to coordinate activities, develop guidelines, facilitate supervision, conduct research, and manage commodities distribution and logistics. The program is implemented in collaboration with various partners. Current projects include the Implementing Best Practices (IBP) initiative, the IUCD Re-introduction initiative, the FP/VCT Integration project, the revision of the PMTCT+ guidelines, development of STI guidelines, development of a community reproductive health package, and establishment of a monitoring and evaluation system.

The program also requires close collaboration with other divisions, especially when promoting integration of services. A family planning working group headed by the DRH exists to coordinate FP programs in the country.

:: Cross-cutting Issues

Community Reproductive Health

It is within families and communities that we live and our practices, behavior, and attitudes are shaped. Many factors that are known to influence RH positively or negatively take place in the context of the

community. Kenya is made up of 43 multi-ethnic groups that range from diverse nomadic groups to agriculturists and urbanites.

Some communities have pockets of high illiteracy, others strongly support and practice female genital cutting, early marriage and cultural practices that violate women's RH rights. Kenya's varied cultural beliefs, behavior, and practices pose major challenges for the provision of quality RH services. However, the community setting, when utilized positively and effectively, can provide a major resource to the government and to citizens for achieving RH goals and objectives. For instance, children orphaned by HIV/AIDS may benefit profoundly when care and support are provided within the communities in which they live. Moreover, risks to expectant mothers may be minimized if communities have knowledge about pregnancy-related complications. There is great need to forge community partnerships in RH and to develop or enhance structures for RH services.

Monitoring and Evaluation

Monitoring and evaluation (M&E) is essential for assessing and improving how policies and programs are designed and conducted. Implementation of M&E should start as early as project planning and design (Rossi and Freeman 1993). The two functions, though related are distinct. According to Bertrand et al. (1996), monitoring in program management is important to:

- Determine how well the program is carried out at different levels and at what cost.
- Track changes that occur from day to day from the resource inputs, production, and use of services.
- Inform management whether the implementation of a program is as planned.
- Determine where the problems are (if any) and what unexpected results have occurred.

Evaluation, on the other hand, can:

- Determine the value of the program.
- Utilize monitoring data to help explain trends in effects and impact of the program/project as well as improve monitoring for better management.
- Determine whether the program/project objectives are being met.
- Identify strengths and weaknesses.

As monitoring covers the ongoing processes of maintaining day-to-day information, it is important to note that evaluation can focus on different program components such as inputs, processes, outputs, and outcomes. Depending upon the purpose of the program, measurements of evaluation could take place at the population level to determine impact of, for instance, a family planning program. In such a case, a random sample of the general population could be utilized. Alternatively, interest could be at the program level, for instance clients participating in an antenatal program (Bertrand et al. 1996).

The DRH seeks to ensure that all priority RH areas utilize M&E tools and that data are maintained at all stages of implementation. The DRH has used a participatory and collaborative approach to harness resources and expertise of CAs, donors, and other agencies to build its capacity for monitoring and evaluation. The DRH is being strengthened to collect and utilize data for decision-making at the national, provincial, and district levels through: developing a training module on utilization of data for decision-making and conducting training using the module; creating a national RH M&E framework with key national indicators identified; and revising current data collection tools for the above indicators. Partners working with the DRH include PSRI, FHI, and MEASURE Evaluation.

SECTION IV

Basics on Research Ethics

:: Introduction

Human participation in research projects has contributed to better quality of life through the development of diagnostic tools and successful treatments. The DRH considers it essential that fundamental ethical principles be included in the design and implementation of all research involving human participants. Although these principles are universal, the availability of the resources needed to maintain these principles is not universal, and the procedures used for the ethical vigilance of research studies may not be optimal. Regardless of limitations, ethical research principles must guide those who plan, conduct, and sponsor research that involves human participants.

:: Fundamental Principles of Human Research Ethics

Human research ethics rest on three basic principles that are considered the foundation of all regulations or guidelines governing research ethics. These principles are:

- Respect for persons;
- Beneficence;
- Justice.

These principles are considered universal, transcending geographic, cultural, economic, legal, and political boundaries.

Researchers, institutions, and in fact human society, are obligated to assure that these principles are followed whenever research involving human participants is conducted. As mentioned earlier, although these principles are universal, the availability of the resources needed to maintain these principles is not universal, and the procedures used for the ethical vigilance of research studies may not be optimal. For instance, no universal principle exists on how a clinical trial should be monitored. Regardless of limitations, these principles must guide the behavior of all individuals involved in planning, conducting, and sponsoring human research.

:: Respect for Persons

Respect for persons recognizes the capacity and rights of all individuals to make their own choices and decisions. It refers to the respect of the autonomy and self-determination of all human beings, and acknowledges their dignity and freedom.

An important component of this principle is the need to provide special protection to vulnerable persons. Children, prisoners, and the mentally ill are examples of vulnerable groups. People with limited education, living in poverty, or who have limited access to health care services are other examples of vulnerable groups. Women might also be considered a vulnerable group. In some cultures women must defer to men in the decision-making process, making true voluntary consent difficult. These conditions may compromise a person's ability to refuse participation.

Respect for persons is embodied in the informed consent process. Informed consent is designed to empower the individual to make a voluntary informed decision regarding participation in the research. Potential research participants must fully comprehend all elements of the informed consent process.

Guidelines for Informed Consent

It is essential to obtain informed consent from participants in a human research study before the study is initiated. The Council for International Organizations of Medical Sciences' (CIOMS) "International Ethical Guidelines for Biomedical Research" contains 15 guidelines for informed consent for research involving human participants. Informed consent is defined as consent given by a competent individual who:

- Has received the necessary information.
- Has adequately understood the information.
- After considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Informed consent embodies the fundamental ethical principle of respect for persons, of their autonomy, rights, and capacity to make informed choices.

Informed consent is not merely a legal requirement or a document to be signed; it is a communication process between the researcher and the participant that starts before the research is initiated and continues throughout the study. It is essential that the information provided is understood by the potential participant and empowers that person to make a voluntary decision about whether or not to participate in the study.

The type, extent, and method of the information provided require the review and approval of an appropriate ethics committee (e.g., the Kenyatta National Hospital ethics review committee).

According to the U.S. code of Federal Regulations, also called The Common Rule, in order to ensure that a research participant receives the necessary information to make an informed decision, it is important to provide each participant with:

- Description of the research and participant's participation, including identification of experimental procedures.

- Description of reasonably foreseeable risks.
- Description of expected benefits.
- Potentially advantageous alternatives to participation.
- Explanation of confidentiality.
- Explanation of compensation for injuries.
- Whom to contact about the research and participants' rights.
- Explanation that participation is voluntary.

The informed consent process is basic to a well-designed, ethically based research study. How informed consent is applied to the research study demands time, creativity, and an understanding of the participant population.

:: Beneficence

Beneficence makes the researcher responsible for the participant's physical, mental, and social well-being as related to the study. Beneficence is also referred to as the principle of non-maleficence, or causing no harm.

The risks to a person participating in a research study must be weighed against the potential benefit to the participant and the importance of the knowledge to be gained. In any case, all risks should be kept to a minimum.

The protection of the well-being of the participant is the primary responsibility of the researcher. Protecting the participant is more important than:

- The pursuit of new knowledge.
- The benefit to science that will result from the research.
- Personal or professional research interest.

:: Justice

Justice refers to the researcher's obligation to distribute equally the risks and benefits of participation in the research study. Recruitment and selection of research participants should be done in an equitable manner. The principle of justice forbids placing one group of people at risk solely for the benefit of another.

For instance, justice would not permit using vulnerable groups—such as minors, poor people, or prisoners—as research participants for the exclusive benefit of more privileged groups.

As with the principle of respect for persons, there is a need to protect vulnerable groups, including the poor and those with limited access to health services.

:: Additional Ethical Considerations

Ethical Considerations for Adolescent Reproductive Health

Legal and ethical guidelines important for conducting adolescent reproductive health (ARH) research include the following criteria (also see "WHO Special Research Guidelines" 2000). When identifying adolescents for research, the researcher should ensure that:

- As the study group, The information gained from the research/ study using adolescents could not be obtained from adult participants.
- The goal of the research will obtain knowledge relevant to the health needs of adolescents.
- The risk presented by the intervention(s) is low and commensurate with the importance of the knowledge to be gained.

- The intervention(s) is intended to provide direct benefit or at least is as advantageous to the individual subject as any other available alternative.
- Among adolescents, younger subjects are not enrolled when older adolescents are scientifically suitable for recruitment as research participants.
- Unless specific legal provisions exist, consent to participate in research should be given only by the adolescents.
- The participation of adolescents who satisfy the condition that the subject be able and capable of understanding the purpose, procedures, risks, benefits, and alternatives of the research is ethically justified.
- The ethical principle of confidentiality for adolescents must be maintained even where consent for the participation involves parental permission.
- Institutions involved in adolescent research must be sensitive to the needs of adolescents and should have the appropriate staff and facilities to care for them.
- In circumstances where researchers believe they are obligated to report adolescent behavior to any authorities including parents, the adolescent must be made aware of the possibility of such reporting prior to their involvement in the research.

However, merely meeting the letter of the law is insufficient. The research community must strive to meet, if not exceed, the spirit contained in the guidelines. In doing so, they place the well-being of the individual research participant before everything else.

Note: For more information on this subject, please refer to Appendix 7 - Selected Bibliography on Research Ethics.

Good Laboratory and Clinical Practices

Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) are covered by the Helsinki Declaration of June 1964, with pursuant amendments in 1975, 1983, 1989, 1996, and 2001. The Declaration binds physicians with the words:

"The health of my patients will be my first consideration."

This is reinforced by the International Code of Medical Ethics, which declares that:

"A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The adapted GLP and GCP are advocated by Kenyan research institutions as applied to use of qualified personnel in research, maintenance of standards of cleanliness, safety in the laboratories, management of documents in the laboratory, quality audit, and calibration of equipment.

Any person intent on carrying out RH research that is laboratory or clinical based will adhere to GLP and GCP as follows:

- Use only trained personnel in all aspects of laboratory work. This must cover all personnel including auxiliary staff.
- Standards of cleanliness shall be maintained at all times. This includes proper airing of laboratories.
- Safety standards must be maintained in the laboratory. Key practices covering clearing passage ways in the laboratory, maintenance of fire extinguishing apparatus, and drilling all staff in their use must be observed.
- Proper labelling of all material in the laboratory should be maintained. No item however small should exist in the laboratory without a label. This is crucial in maintaining safety in the laboratory.

- Laboratories being used for RH research should maintain quality audit so that their standards are acceptable to other laboratories.
- All equipment in the laboratory should be properly calibrated as a way of maintaining accuracy, precision, and reproducibility.

Good Clinical Practices are applicable to clinicians who plan to carry out clinical RH research involving human participants. A case in point is where a trial of drugs is involved. The researcher should observe and adhere to the 12 principles adopted by the 18th World Medical Assembly, Helsinki, Finland 1964 and paraphrased in the following guidelines:

- RH research involving humans must conform to scientifically accepted principles, a thorough knowledge of existing literature, and proper laboratory experimentation.
- Every experimental procedure should be clearly outlined in a research protocol that must be subjected to independent review that will check its adherence to laid down components of a standard protocol.
- No RH research involving humans will be conducted unless expected outcomes/benefits outweigh insignificant risks to the human subjects. In all circumstances, the interests of the human subject must override the interests of science and society.
- RH research must safeguard the integrity of the individual, by respecting the privacy of the subject, and minimising the impacts of the study on the subject's physical and mental integrity and personality.
- No RH research involving humans will be carried out unless hazards involved in so doing are known and predictable.
- Publication of findings from RH research must be accurate.
- All RH research must inform the participants about the aims, methods, benefits, and potential hazards of the research and that one is at liberty to take or not take part in the research. Consent to participate must be obtained from the subject in a non-coercive manner. An authorised adult should give assent for minors.

- In cases where legal incompetence is observed, a legal guardian must obtain consent from the participant in accordance with the laws of Kenya.
- The research proposal/protocol must contain an undertaking that ethical considerations as outlined in this guide and the principles stated have been complied with.
- The proposal indicates how the confidentiality of information obtained from participants will be maintained.

Ethics and Good Laboratory/Clinical Practices

Researchers are required to:

- Agree to abide by regulations that govern research in their institutions of affiliation.
- Replace any materials made available to the researcher that are lost or damaged during the process of research.
- Use or dispose of any material made available to them in a manner that is not prejudicial to the interests of Kenyans.
- Obtain the consent of their institutions of affiliation to complete any research outside Kenya and to export any material to other countries.

All research proposals that intend to use experimentation as a method of data collection MUST state on the cover page the declaration that it will respect all the rights of the subjects to the participants by providing full knowledge of what the research is all about and a clear statement of how they will benefit from the products. The statement MUST undertake to respect the dignity of the subjects and protect them from any harm emanating from the process of experimentation in accordance with Section 4 of this document addressing ethical standards in research.

All research utilising experimentation as a method of data collection will state the following:

- Describe the exact experimental design that will be used.
- If the stimuli will be administered once and observations on the subject made, indicate how the outcome will be attributed to the stimuli.
- Explain how control groups will be set up to deal with extraneous factors such as the frustration of the subject, events that change the course of experimentation, the effects of any equipment used, and reaction to the process of stimuli application.
- Explain how the research will deal with mortality or participants who drop out from the study.
- State how the experiment will deal with interaction effects between groups receiving the stimuli and those that do not receive the stimuli.

:: National Council for Science and Technology Regulations on Research Clearance and Implementation

Legal Provisions

The National Council for Science and Technology (herein referred to as the Council) is empowered under the Science and Technology Act (1979) to coordinate all research work in Kenya and advise the government on all matters of science and technology. This among other things entails authorizing and documenting all research work in Kenya.

The Council is responsible for assessing technical and ethical aspects of proposals submitted for clearance and authorization. It is illegal to conduct research in Kenya without clearance. The offence is punishable as provided for in the Science and Technology Repeal Act Cap 250 of the Laws of Kenya.

Objectives of Research Clearance and Authorization

Under the Science and Technology Act, the objectives of research clearance are to:

- Facilitate coordination of research.
- Encourage quality research that will directly benefit Kenya and increase the body of scientific knowledge as a whole.
- Make secure the data and results of research work undertaken in Kenya.
- Document and monitor all research work going on in the country and have centrally available information on such work.
- Facilitate useful research work and discourage projects that are not in the national interest.

- Ensure maximum benefit and dissemination of knowledge and technology to users from research activities in the country.
- Eliminate unauthorized collection and transfer of research information and materials.
- Ensure that research in Kenya is conducted according to professional ethics.
- Ensure that relevant national institutions are informed of intended and ongoing research works in their areas of responsibility and that they are given an opportunity to influence the course of research works in their areas of interest.
- Discourage unnecessary duplication of data collection for ongoing research projects or research already undertaken or research about to be undertaken.
- Protect national interests in general and as far as possible discourage clandestine activities that may be undertaken under the cover of research.

Monitoring and Evaluation of Authorized Projects

- The government of Kenya shall have access to the data and the research premised by the project.
- The Council may from time to time visit the research projects to become familiar with the work under way and make appropriate recommendations on the project.
- The affiliating institutions will be required to give progress reports to the Council and to indicate areas that need further action if considered necessary.
- Final research reports will be deposited in the Council library with copies to affiliating institutions, the National Archives, and the relevant ministry.

Issuance of Research Permit

- The research permit will be issued in the name of the holder of the permit as defined below.
- The holder of the permit will be the project leader or the expedition leader or the leader of the institution in the case of standing research clearance.
- The holder of the research permit will be responsible for making sure that the regulations governing the permit are observed.

Termination of Research Permits

The government reserves the right to withdraw a research clearance permit (individual or standing) without giving notice or reasons to the researcher or institution.

Work Permits

Foreigners working in Kenya are required by law to secure work permits. Granting of a research permit does not in any way absolve the researcher from the requirement of a work permit. It is up to the researcher to secure the necessary work permit upon arrival in Kenya.

Application for clearance for non-Kenya assistants in research projects will be carefully considered but is generally disapproved where it is obvious that Kenyans can be recruited for such tasks.

Acknowledgement of Collaborators

Researchers are required to acknowledge Kenyan collaboration and participation in all papers and books that emanate from the research.

The Kenyan government research permit must be acknowledged. The affiliating institutions must be acknowledged and its mailing, physical and e-mail addresses and the telephone contact must be given.

APPENDICES

Appendix 1

Reproductive Health Research Agenda Setting in Kenya - June 2004

:: Executive Summary

Background

The Ministry of Health is committed to providing the best possible reproductive health services in the country. In that spirit, a workshop was held in Nairobi, Kenya, followed by a series of interviews with practitioners and experts in the field. The purpose of the workshop and the subsequent interviews was to learn, from those most actively involved, what are the gaps in reproductive health programs and how research can be used to address those gaps. The priorities identified by the participants of this workshop are seen as an important step in fulfilling the government's promise of reproductive health for all of its citizens. The components of reproductive health are contained in the National Reproductive Health Strategy for Kenya and form a core of RH services provided. These include unmet needs for family planning, safe motherhood and child survival, management of STDs/HIV/AIDS, adolescent health, infertility, gender issues and reproductive rights, and chronic illnesses and cancers of the reproductive system.

Purpose

The Ministry of Health (MOH) understands that research, when properly applied, can be an essential tool in addressing obstacles to optimum reproductive health. The purpose of the workshop was to solicit views from a cross section of stakeholders and partners so that government and independent agencies could identify issues open to research, establish an agenda for those issues, and identify questions that can support program improvements. This report is based on

the consultation and participation of a broad range of stakeholders through the one and a half day workshop.

Results

The research priorities were derived from the challenges and problems facing reproductive health in Kenya. Although this report is specific to reproductive health, the challenges identified are considered identical to those affecting the country's overall health delivery system. The workshop participants pointed to inadequate space, insufficient training and inadequate numbers of health care workers, limited access to health care in general, poor community involvement, reluctant partners, harmful socio-cultural practices, lack of innovation and creativity in PMTCT services, stigma and discrimination, lack of programs for marginalized groups, inadequacy of IEC intervention and materials, poor collaboration, and insufficient equipment and supplies. Research must be a permanent and continuous feature of any health program. However, resources are limited and it is impossible to carry out research in all programs. Therefore, research priorities are based on program needs, major health challenges, institutional capacities and capabilities, and available resources. Below, listed in relative importance, are areas open to research and suggested lines of productive questioning:

Family Planning and Contraception

Research should study the effects of knowledge attitude and practice on contraception as well as the status of contraceptive security, procurement and logistics. Contraceptive security is the greatest challenge to family planning and is inextricably linked to a reduction in fertility. The latest study (2003 KDHS) indicates a significant and worrying trend in the rise of fertility levels from 4.7 in 1998 to a level of five in 2003. The KDHS also shows a plateau of the CPR at 39%. The factors contributing to these trends urgently need to be identified as part of this research agenda.

Safe-Motherhood

It was generally felt that a substantial amount of work has been carried out in the safe motherhood program; however, at the rate of 590 deaths out of 100,000 births, the decline in maternal mortality is slower than desired. Research needs to determine how we measure the effectiveness of maternal health programs and what effect the programs and interventions have on reducing maternal mortality. The MOH needs to know what effect knowledge, attitude, and practices have on pregnancy and its complications, specifically, why health care workers and families have a low understanding of complications that can occur during pregnancy and delivery.

HIV/AIDS/STDs

The current challenges include reducing transmission, prolonging lives through drug therapy, the treatment of opportunistic infections, the stigma associated with HIV/AIDS, contraceptive use, effective interventions, training of health workers, prevention of pregnancy, infant feeding, and a wide-ranging, varied list of other challenges . These are discussed at length in this report. Just as the challenges are far-reaching, so are the beneficial applications of research.

Gender Issues

Gender issues cut across reproductive health. The main issue is the mainstreaming of gender in all HIV/AIDS/ STI/PMTCT programs. Some of the questions open to research include policy compliance to gender considerations, the extent to which the existing policies and practices protect reproductive health rights, and the extent to which the government adheres to international conventions and declarations.

Reproductive Health in Adolescents and Young People

A great deal needs to be done to make the plight of adolescent reproductive health more visible. Research needs to explore the

epidemiology of adolescent problems and studies on adolescent health and the welfare information system that, in the next five years, can culminate in good record keeping. As is true throughout Kenya, research must address HIV / AIDS and how best to prevent and treat the disease using interventions, peer counselling, teacher and mentor guidance, and other programs meant to reach and teach a young audience.

Cancers of the Reproductive Systems

Cancers form some of the most formidable challenges to health in Kenya. There has been an inadequate investment in commitment, time, thinking, and resources to the problem. The questions raised revolve around policies, programs, community awareness, and positioning health workers to provide care and support.

Recommendations

A deadline should be set for the acceleration of the remaining issues so that they can be brought forward and specific responsibilities assigned to the different parties involved in RH research.

A cross section of partners in RH research should forward their information to the DRH for inclusion in the central inventory. The DRH should inform all partners involved to forward any research results, as well as plans for future research activities. DRH should also build an information base by developing, updating, and advertising a website where all local and international players can forward any available research work.

Efforts should be made to disseminate this workshop's conclusions. The DRH should improve the method of identifying priorities and develop a guide for future researchers and research organisations.

Finally, the DRH should keep itself open to other ideas.

Full report: *http://www.drh.go.ke/documents/RH%20Research%20Agenda%20Report.pdf*

Appendix 2

The DRH Research Submission Checklist

Date Submitted: _____
Completed by: _____
Proposal Title: _____
_____

Institutional Contact Information:

Name:_____

Address: _____

Email: _____

Phone:_____

Fax:_____

The DRH Focus Area Being Addressed by Proposed Research:

- ☐ Safe Motherhood and Child Survival
- ☐ Adolescent Reproductive Health
- ☐ Family Planning and STIs, HIV/AIDS
- ☐ Gender and RH Rights
- ☐ Community Reproductive Health
- ☐ Monitoring and Evaluation
- ☐ Other: _____

Location of Activity

_____

PROJECT DESCRIPTION

Background / Potential for Public Health Impact:

_____

_____

_____

_____

Basic Study/Subproject Design and Methods:

Objectives

1. _____ _____

2. _____

3. _____

4. _____

5. _____

Study Site(s):

_____

_____

Study Population:

_____

_____

Brief Statement of Study Design and Sample Size Selection:

_____

_____

Description of the Methods for Data Collection:

_____

_____

Expected Outcomes:

_____

_____

Feasibility of Conducting Research:

_____

_____

Potential for Scale-up and/or Replication and Utilization:

_____

_____

Ethical Considerations:

_____

_____

Implementing/Collaborating Agency(s):

_____

_____

DRH collaboration requested:

Yes: No:

Proposed budget: KShs _____

Please include a curricula vitae of each investigator (if collaborating with the DRH).

Please submit this form to:
The Head, Division of Reproductive Health,
PO Box 43319, NAIROBI, KENYA
Tel: 254-20-2725105
Fax: 254-20-2716814
Email: drh-head@africaonline.co.ke

Appendix 3

CONCEPT PROPOSAL REVIEW FEEDBACK FORM
FOR OFFICIAL USE BY DRH REVIEW GROUP ONLY

Rationale for Rating: (Provide 3-5 sentences summarizing the group discussion concerning this proposal to inform both the DRH Program and as feedback to the person who submitted the proposal.)

Date Reviewed: Review Team Leader:

_____

Assigned Reviewers:

1. _____

2. _____

3. _____

Review Priority Determination:

___ Approved for collaboration

___ DRH cannot collaborate

Meeting Date: _____

Appendix 4

:: DRH Document Tracking Form

FOR OFFICIAL USE ONLY

Research Title: _____

Institutional Contact: _____

Expected Completion Date: _____

Concept Paper Submitted: _____

☐ Electronic Copy

☐ Hard Copy

Checklist Submitted: _____

☐ Electronic Copy

☐ Hard Copy

Abstract of Findings Submitted to the DRH Resource Centre

☐ Electronic Copy

☐ Hard Copy

Final Report Submitted to the DRH Resource Centre

☐ Electronic Copy

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Appendix 5

:: National RH Research Stakeholders Meeting to review draft guidelines – 28th October 2004

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:: National RH Research Stakeholders Meeting to review draft guidelines – 28th October 2004

Name	Position	Organization
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Appendix 6

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Appendix 7

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