

KORLE BU TEACHING HOSPITAL



RESEARCH POLICY GUIDELINES AND PROCEDURES

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ABBREVIATIONS

DPDM:	Diploma in Project Design and Management
EU:	European Union
FDA:	Food and Drug Authority
GCP:	Good Clinical Practice
GMP:	Good Manufacturing Practice
HODs:	Head of Directorate(s)
HSR:	Health Service Research
ICH:	International Conference on Harmonization
IEC:	Independent Ethics Committee
KBTH	Korle-Bu Teaching Hospital
KBTH IRB:	Korle-Bu Teaching Hospital Institutional review board
KBTH-RAC	KBTH Research and Advisory Committee
MOU:	Memorandum of Understanding
OR:	Operational Research
PI:	Principal (Research) Investigator
R&D:	Research and Development
RCT:	Randomized Controlled Trial
SMS:	School of Medical Sciences
SOPs:	Standard Operating Procedures
STC:	Scientific and Technical Committee
USA:	United States of America

DEFINITIONS

Medical Research versus Medical Practice: There is a distinction between “medical research and “innovative medical Practice” which is determined by the intent. In medical practice the sole intention is to benefit the individual patient consulting the clinician, not to gain knowledge of general benefit, though such knowledge may emerge from the clinical experience gained. Whereas in medical research, the primary intention is to advance knowledge so that patients in general may benefit. In this case, the individual patient may or may not benefit directly.

Operational research (OR): This is the discipline of applying analytical methods to help make better decisions. Typically concerned with optimizing the maximum e.g. patient satisfaction, performance, crop yield, profit, etc. or minimum e.g. Loss, risk, etc. of some objective function.

Operational research helps management achieve its goal using the scientific process. When faced with a new problem, operational research is expected to determine which techniques are most appropriate given the nature of the system, the goals for improvement, and constraints on time and computing power. For this other reasons, the human element of OR is vital.

Health service research (HSR): This is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies and personal behaviors affect access to health care, the quality and cost of health care, and quantity and quality of life.

Studies in health services research examine outcomes at the individual, family, organizational, institutional, community, and population level. The primary goals of health services research are to identify the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety. Findings from health services can be applied by physicians, nurses, health managers and administrator, and other people who make decisions or deliver care in the health care system.

Patient-oriented research: Research conducted with human subject (or no material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies.

Principal investigator (PI): The main researcher overseeing or conducting the research process.

Ethics committee: An independent group of professionals often complimented by a non-scientific member of the public responsible for approval of study protocols before a study is actually carried out. Subject safety and scientific integrity of the protocol are the main concerns. In KBTH the ethics committee is known as the Institutional Review Board (KBTH IRB).

Study Protocol: The document describing the rationale, the subject population, the drugs/products/approach to be used and the full time schedule of the study as well as the endpoints to be evaluated.

Observational study: A study in which the investigators do not manipulate the use of, or deliver, an intervention (e.g. do not assign patients to treatment and control group), but only observe patients who are (and sometimes patients who are not as a basis of comparison) exposed to the intervention, and interpret the outcomes.

Cohort study: An observational study in which outcomes in a group of patients exposed to a putative factor of interest are compared with outcomes in a similar group of patients not exposed (control group) , either prospectively or historically.

Case-Control Study: A retrospective observational study designed to determine the relationship between cases (patients with the outcome of interest) and controls (patients without the outcome of interest).

Cross-Sectional Study:

An observational study that examines the relationship between diseases (or other health-related characteristic) and other variables of interest as they exist in a defined population at a particular time. In such studies, prevalence measures rather than incidence is normally recorded.

Clinical Trials: Trial to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on large groups of people.

Randomized controlled Trial (RCT): A person experiment in which investigators randomly assign eligible sample of patients to one or more treatment groups and control group and follow patients' outcomes. It's normally used for testing the efficacy or effectiveness of healthcare services (such as medicine or nursing) or health technologies (such as pharmaceuticals medical devices or surgery).

Non-randomized controlled Trial: An experimental study in which people are allocated to different interventions using methods that are not random and the aim of which is to test for efficacy or effectiveness on an intervention.

Good clinical Practice: A standard to ensure protection of research subjects and data integrity in clinical studies of new drugs/product.

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Forward

Research and development plays a major role in the strategic framework of the Korle-Bu Teaching Hospital. The various clinical areas are all already involved in some form of research, but there is the need to harmonize all such research activities. This will invariably improve sharing of results with regional, national and international partners leading to better practice outcomes. It will also have a positive impact on monitoring and evaluation of research activities within the hospital.

For an emerging country like Ghana, the need for cutting edge research cannot be over-emphasized. However good health research is always underpinned by adherence to guidelines, ethical conduct of research and to rights and well-being of participants. These call for an appropriate legal framework with ethical standards well understood by all stakeholders (researchers, sponsors, participants, health authorities). The KBTH research policy will guide all research in the hospital

An Institutional review board for KBTH will turn the hospital into a strategic location for collaborative research work with international counterparts. This will benefit not only patients who patronise the hospital, but the larger population as well.

Mr Daniel Ankrah

Chair, Technical committee

Chapter 1 INTRODUCTION

1.1 Background to KBTH

Korle-Bu Teaching Hospital (KBTH) is located in Accra, Capital of Greater Accra region. The Korle Bu Teaching Hospital has moved from an initial 192-bed capacity hospital to become a leading national Centre in Ghana and the third largest hospital in Africa.

The Hospital, as at 2012, has over 2,000 beds, 21 clinical and diagnostic Departments/Units and three “Centres of Excellence”. Currently, it has over 4,000 medical and paramedical staff with an average daily attendance of 1,500 patients, about 250 of which are admitted.

“Korle Bu” which in Ga parlance means ‘the valley of the Korle lagoon; was established on October 9, 1923 as a General Hospital to address the health needs of the indigenous people under the administration of Sir Gordon Guggisberg, the Governor of Gold Coast.

By 1953, population growth and the proven efficacy of hospital-based treatment caused a rise in hospital attendance. The demand for this form of treatment rose so high that the then government was compelled to set up a taskforce to study and make recommendations on how the Hospital could be expanded to meet the rising patient numbers.

The recommendations of the taskforce were accepted by the government and their implementation resulted in the construction of new structures, such as the Maternity, Medical, Surgical and Child Health blocks. This increased the Hospital’s bed capacity to 1,200.

Korle Bu Hospital became Korle Bu Teaching Hospital in 1962 when the University of Ghana Medical School (UGMS) was established for the training of medical doctors. Currently, the UGMS and five other constituent schools are subsumed under the College of Health Sciences to train an array of health professionals. All the institutions of the College undertake their clinical training and research in the Hospital.

MISSION

We are committed to provide quaternary health care facilities and services, training, research, outreach and advocacy for clients within and outside Ghana.

VISION

To become the preferred centre of excellence and innovation for specialist healthcare provision, training, research and advocacy in Ghana and West Africa.

KBTH recognizes the need for targeted research and development as a key component of being able to achieve our vision, in addition to fulfilling one of its core mandates as a teaching hospital to conduct research. It is for this reason that the Research and Development (R&D) Policy document has been developed.

1.2 KBTH's Research and Development Concept

One of the KBTH's core mandates as a teaching hospital is to conduct research. Research is systematic investigation that includes development, testing and evaluation, and activity which is designed to develop or contribute to generalizable knowledge.

KBTH's Research and Development refers to any activity aimed at resolving scientific or technological uncertainty resulting in the advancement of science or technology. The advances includes:

- New or improved products e.g. a new drug, vaccine or diagnostic tool
- Processes e.g. a new surgical technique
- New treatment protocols
- Services and knowledge's e.g. an efficient appointment system or improved bed occupancy.

An increase in the level of R&D activities as part of KBTH's core business will stimulate innovation and help raise productivity. R&D activities include:

- Indigenisation (adoption of locally appropriate technologies)
- collaborations and learning from other health institutions
- improving existing procedures, products and services
- producing new knowledge or coordinating/fitting into national health systems
- reviewing the core business of the hospital

1.3 Challenges with Research in KBTH

- a. Much research has taken place and is on-going in KBTH; in an uncoordinated fashion. Leading to KBTH's inability to realize the full benefits from research:
 - i. Impact to the skills and knowledge acquired on KBTH' services delivery(through the application of research findings to improve on clinical and non-clinical service delivery)
 - ii. Materially, (by way of equipment, training opportunities for staff etc.);
 - iii. Intellectual Property (IP)
 - iv. Financially (through administrative charge, consultancy fees etc.);
- b. It is important that research in KBTH is streamlined so that maximum benefits can be derived for improved service delivery, contribution to knowledge both nationally and internationally as well as for the benefit of the investigators themselves.
- c. KBTH at present cannot demonstrate a clear laid-out hospital-wide to long-term research strategy. KBTH therefore intends to promote operation and patient-oriented research aimed at improving service delivery and management practice. This will involve building the research capacity of the hospital.

Chapter 2 GUIDELINES AND PROCEDURES

2.1 Introduction

The KBTH Research and Development guidelines are a set of principles, regulations and standard of good practice. Adherence to these is expected to continuously improve the quality of research and the healthcare system in the Teaching Hospital (see figure 1). It is important that researchers are aware of their obligations to KBTH's healthcare research governance and process. Any arrears of uncertainty in the application of these guidelines should be reoffered to the RD.

2.2 Importance of Research and Development Guidelines

These guidelines are necessary in order to:

- Safeguard participants in research
- Protect researcher/investigators (by providing a clear framework to work within)
- Enhance ethical and scientific quality
- Promote compliance
- Promote good practice and ensure lessons are learned

2.3 Scope

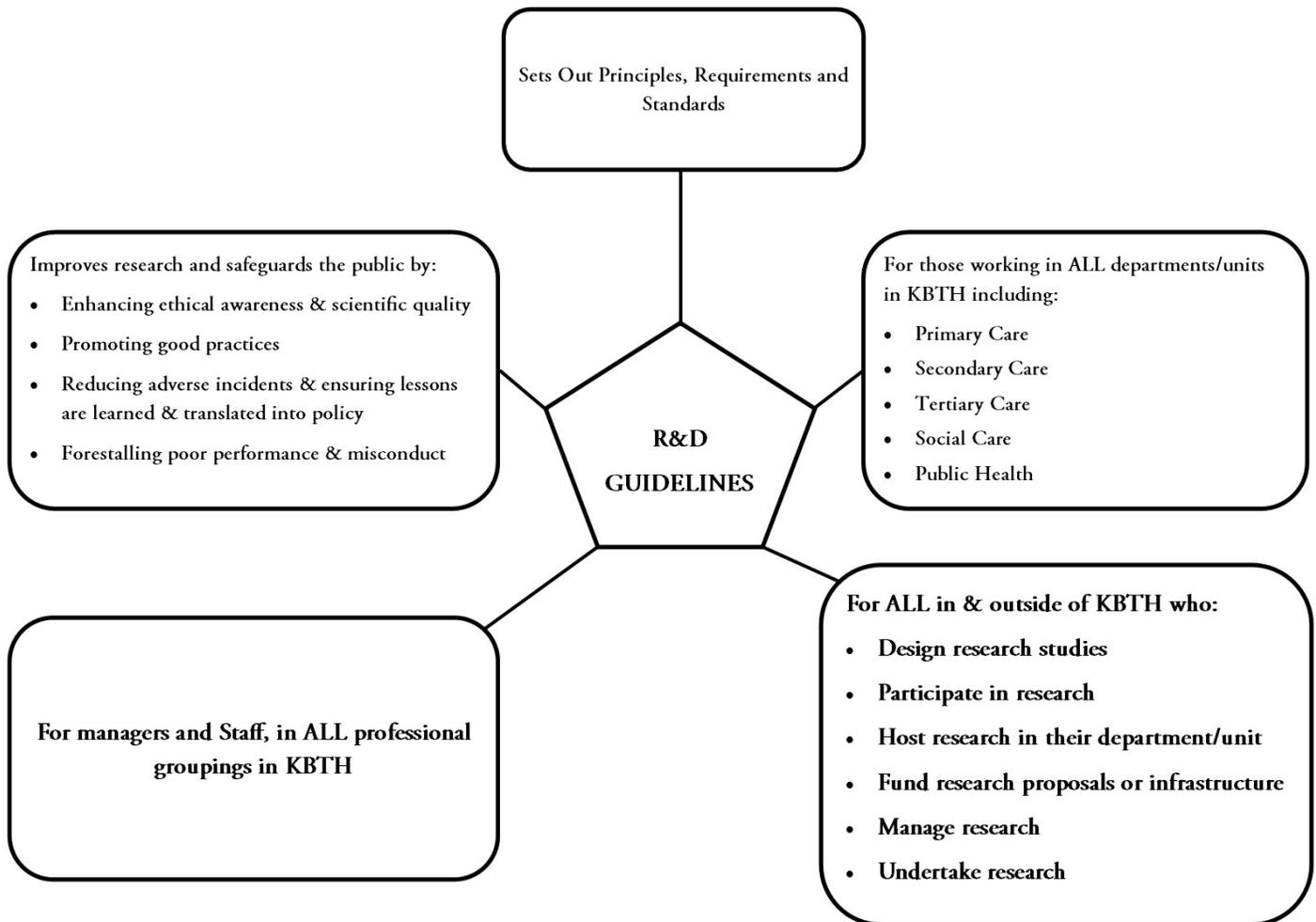
KBTH's Research and Development Guidelines applies to every study/research being conducted in KBTH or involving KBTH staff. The study/ research may involve living human subjects, human remains, cadavers, their tissue or biological fluids and/or data. Examples of such research in KBTH include but are not limited to:

- Use of data from a patients' medical record
- Observations and interviews
- Conducting surveys
- Using invasive/non-invasive imaging
- Using blood, skin or other tissue samples
- Inclusion in trials of drugs, surgical procedures or other treatment (Clinical Trials)

A number of different individuals and organizations are involved in health and social care research in KBTH including:

- Hospital and non -hospital workers
- Universities
- Students and their supervisors
- Research Ethics Committees
- Pharmaceutical and other industries

Figure 1: R&D OPERATIONS OF THE R&D



2.4 Research Culture

Key elements of good research at KBTH include:

- Respect for participant’s dignity, rights, safety and wellbeing
- Acknowledgement of the diversity within society
- Personal and scientific integrity
- Leadership
- Honesty
- Accountability
- Openness
- Supportive management

2.5 Principles and Standards

This document sets out principles and standards for research in KBTH under four domains.

- Ethics and Sciences
- Information
- Health and safety
- Finance and intellectual property

2.5.1 Ethics and science

Research should adhere to the following key ethical principles

1. Respect For Persons
2. Beneficence
3. Justice

In addition, research should:

1. **When it involves KBTH patients, other service users, care professionals or volunteers or their organs, tissues or data; be reviewed independently to ensure ethical standards are met. The ethical review process via the KBTH IRB is a requirement.**
2. Be peer reviewed by the KBTH IRB to offer independent advice on its scientific quality. For student's research projects, the supervisors are responsible for ensuring the review.
3. Ensure that the dignity, rights safety and wellbeing of participants are protected in any research study.
4. Have an identified sponsor, who will take on responsibility for initiation, management and financing of a study. The sponsor must, amongst other things be satisfied that ethical standards are being followed.
5. Recognizing that consent is at the heart of ethical research, all studies directly involving individuals must have appropriate arrangements for obtaining consent. Care is needed when seeking consent from children and from vulnerable adults such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form and that the role and responsibilities of parents, care providers or supporters are clearly explained and understood.
6. Use human tissue, organs, blood etc. appropriate. Consent from patients or relatives of deceased persons is required.
7. Use and protect patient's data appropriately. All those involved in research must be aware of their legal and ethical responsibilities. Particular attention must be given to systems for ensuring confidentiality of person information and to the security of those systems.
8. Involve service users and cares of their representative groups, whatever possible, in design, conduct and reporting.
9. Respect the multi-cultural and diversity of human society and conditions.
10. Take account of risk to participants. Risk must be explained clearly to the KBTH IRB.
11. Consider existing sources of evidence, especially systematic review. Research which duplicates other work unnecessarily, or is not sufficient quality to contribute usefully to existing knowledge, is unethical and discouraged in KBTH.

12. Be approved by the Ghana Food and Drugs Authority (FDA) if it involves the trials of medicines and other health products in people.
13. Meet existing legal requirements governing the use of human embryos, the release of genetically modified organisms, and food and food processes, as appropriate.
14. Protect the data collected for an appropriate stipulated period to allow further analysis by authorized groups or individuals subjects to consent, and support monitoring by regulatory and other bodies.

2.5.2 Information

1. Health and social research is conducted for the benefit of patients, users, care professionals and the Public. The R & D shall make public available information on research being conducted in KBTH/by KBTH employees. The R & D shall collaborate with KBTH IRB to provide this information.
2. Findings must be made accessible to study subjects and potential beneficiaries.
3. For commercial development of medicine, diagnostics, medical devices and aids etc. consideration must be given to the protection of KBTH'S intellectual property or commercial confidentiality. The timing of the publication for research findings should take account of this.
4. KBTH encourages Open Access publishing.

2.5.3 Health and Safety

1. Research may involve the use of potentially dangerous equipment, substances, organisms or human specimens. The safety of subject and researchers must be a priority at all times.
2. Health and safety regulations must be strictly observed – including the provision of information, containment, shielding and monitoring, as required.
3. Group insurance should be considered in studies likely to put subject at significant risk.

2.5.4 Financial and Intellectual Property

1. There must be transparency and accountability in the use of both KBTH and external funds to support health and social care research.
2. All research being conducted in KBTH or utilizing KBTH'S human/physical infrastructure in any way, which is not funded by KBTH, must pay administrative charge to KBTH.
3. Consideration must be given to intellectual implication of the research being conducted ensuring that public health benefit will not be limited.
4. For every research contract signed, KBTHs intellectual property interest shall be clearly defined and protected.

2.6 Process for commencing research activities in KBTH

KBTH is committed to supporting high quality research across all directories and units. Research and developments is regarded as integral to the provision of high quality evidence based care.

KBTH while acknowledging that following due process can sometimes become complex and frustratingly bureaucratic, is committed to making this process as clear and smooth running as possible for researchers. Note that, this process must be pursued taking cognizance of the IRB's standard operating procedures (SOP). Further information on this process as well as the KBTH IRB is available from the KBTH IRB or the R & D. **Note that all research activity taking place in KBTH must have a Ghanaian Principal Investigator (PI) or Co –PI.**

The process described below is to be followed if the research to be conducted meets any one or more of the following:

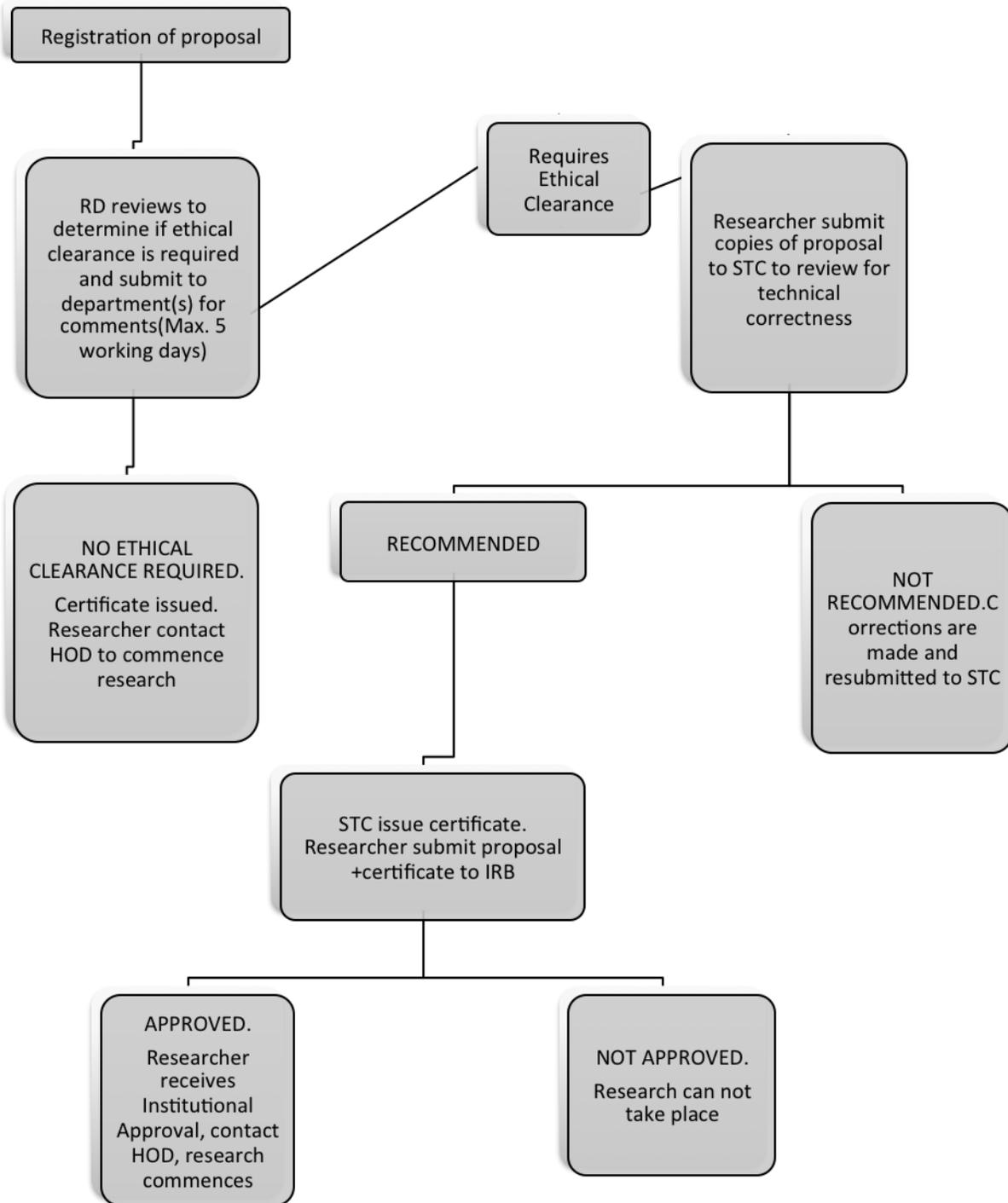
- The research will be conducted in KBTH
- The researcher will in any way cite KBTH before/during/after completion of the research

Research Application Procedure:

1. The researcher shall register his/her proposal study by completing an application form, attaching the research proposal to the registration form and submitting to the R& D secretariat. Remember that all research being conducted in KBTH must have a Ghanaian (preferably a KBTH employee) as a PI or co-PI. ALL APPLICATIONS ATTRACT A FEE.
2. The registration forms are to be filled electronically on the website or manually by downloading form from kbth.gov.gh/research, filled and submitted to the R & D secretariat.
3. The R & D shall review the submission to determine whether it would require IRB, shall record into data base and submit it to the head of directorate(s)/unit(s)(HOD) relevant to the study for comments/expression of any concerns.
4. If following five working days no comments are received from the HOD(s) the submission shall be considered as without comments from the directorate(s)/unit(s) relevant to the research and shall proceed to the next stage. The researcher will be notified if no further requirements (i.e Not requiring IRB etc) are needed and may now re visit the R & D to pick/his or her certificate.
5. If however the HOD(s) have concerns, the R & D shall mediate by facilitating a discussion between the researcher and the HOD(s). Following resolution the researcher will be notified and may now re visit the R & D to pick up his/her certificate. If however resolution is not achieved the research cannot be conducted.
6. If it is determined that the researcher does not require IRB review the researcher shall contact the relevant HOD(s) for a date to commence the work. Official notification of commencement date shall be either by minutes on the ethical clearance letter, a memo or a letter
7. On the other hand, if it is determined that the researcher requires IRB review, following registration, copies of the proposal shall be submitted to the R & D for review by the Scientific and Technical Committee (STC) for technical correctness and issue a certificate.

8. The researcher will then be required to make the requisite submission to the KBTH IRB along with a copy of the registration certificate issued by the STC. The KBTH IRB is expected not to accept submissions that do not have an attached STC certificate.
9. After following the process laid down by the KBTH IRB if ethical clearance is not granted the research cannot take place.
10. However if clearance is granted in writing by IRB, the researcher then receives the institutional approval from the Medical Director and then contacts the relevant HoD (s) to commence the work. Official notification of commencement date shall be by either minutes on the ethical clearance letter a memo or a letter.
11. Once the research is underway, the researcher is required to abide by all the guidelines in this document as well as any specific directives that may have come from the KBTH IRB, R & D or KBTH's management.

Figure 2: PROCESS FOR COMMENCING RESEARCH IN KBTH



2.7 Sponsored research

In this document, funded research refers to all research being funded from external, internal (KBTH, College of Health Sciences, Government of Ghana) and other sources (including personal and not third- party)

Where externally funded research involves KBTH in relation to employee's time resource and infrastructure, the following are to be noted;

1. Aside the agreement signed between the PI and the sponsor, there must also be an agreement with KBTH that clearly defines the relationship between KBTH and the PI and /or the sponsor. This may take the form of the sponsor signing an agreement directly with KBTH or the PI signing an agreement as per the above
2. Funded research must clearly described KBTH's time resources and infrastructure required by the project. When available, all funds for research must be fully disclosed in detail in the agreement signed between KBTH and sponsor as per point 1. This includes remuneration to the PI, project staff, cost of equipment etc.
3. Where funds for research are lodged with KBTH they shall be managed (including purchase of equipment and materials) by KBTH (director/unit accountant or central accounts) in accordance with the contract /MOU and prevailing institutional requirements without any disadvantage to the PI
4. Where there are no caps, not less than 10% shall be paid by the sponsor /PI as administrative charges.
5. The following shall be exempted from paying administrative charges
 - a. Hospital projects
 - b. Grant-in-aid sponsored projects
 - c. Local student project.
6. Projects involving collaborating partners and others not specified in this section shall be considered on their individual merit
7. Where research funds are lodged with UG and the research site is KBTH the administrative charges be split between the two institutions

Chapter 3 RESPONSIBILITIES AND ACCOUNTABILITIES

3.1 Introduction

Persons involved in research should be conversant with the principles of good practice relating to ethics and science; information health and safety as well as finance set out in this document. They should also be appropriately qualified both by education and experience to carry out their roles in the research

A complex array of organization and individuals may be involved in a health or health related research study. It is therefore essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.

The allocation of responsibilities shall be as follows:

3.2 Investigators

Chief/principal investigator (PI): the PI must be an individual with requisite experience, expertise and training to design, conduct and analyze the result. The PI also has overall responsibility for the research.

The PI shall ensure that:

- The research team gives priority at all time to the dignity rights safety and well-being of subject
- The study complies with legal institutional and ethical requirements
- The research is carried according to the standard in this document
- Each member of the research team is qualified by education/training/experience to discharge their role in the study
- All members of the researcher team have adequate training, support and supervision.
- Non staff of KBTH involved in the research have received the relevant permission from KBTHs management. Non staff performing responsibilities regulated by existing professionals bodies in Ghana must have obtained the requisite license
- When a study involves subjects under the care of another not directly involved in the study they are informed that their patients are being invited to participate
- For clinical trials involving medicines, the research follows all conditions imposed by the FDA
- Procedures are in place to ensure collection of high quality accurate data and to maintain the integrity and confidentiality of data during process and storage.
- Arrangements are in place for the management of any intellectual property and feed-back as appropriate to research participants
- Once established, findings from the work are disseminated promptly and feed-back as appropriate to research participants
- There are appropriate arrangements to archive the data when the research has finished and to ensure it is still accessible
- All data and documentation relating to the trail are available at the request of the inspection and auditing authorities.

Investigator: Person responsible, individually or as leader of the researchers at a site for the conduct of a study or at the site for clinical trials involving medicines. An investigator must be an authorized health professional.

The investigator is responsible for:

- Developing protocols that are scientifically sound and ethical
- Submitting the design for independent expert review
- Conducting the study to the agreed protocol (or proposal) in accordance with legal institutional and ethical requirements
- Preparing and providing information for participants
- Ensuring subject's welfare while study is on-going
- Arranging to make findings and data accessible following expert review
- Feeding back result of research to participants.

3.3 Main funds provider

- i. The main organization or individual providing funding for a study
- ii. Key responsibilities of the main funder includes
- iii. Assessing the scientific quality of the research as proposed
- iv. Establishing the value for money of the research as proposed
- v. Considering the suitability of the research environment in which the research will be under taken particularly the experience and expertise of the chief investigator principal investigator(s) and other key researchers involved.

Requiring that a sponsor takes on responsibilities before the research begins

3.4 Sponsor

Individual organization or group taking on responsibility for securing the arrangements to initiate manage and finance a study (a group of individuals and/or organization may take on sponsorship responsibilities and distribute them by agreement among the members of the group. Provided that, collectively they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

Key Responsibilities of the sponsor include:

- Confirming that everything is ready for the research to begin:
- Taking on responsibility for putting and keeping in place arrangement to initiate manage and fund the study
- Satisfy itself that, the research protocol ,research team and research environment have passed appropriate scientific quality assurance
- Satisfy itself that the study has ethical approval before it begins.
- For clinical trials involving medicines, seeking a clinical trial authorisation and making arrangements for investigational medical products.

- Satisfy itself that arrangements are kept in place for good practice in conducting the study and monitoring and reporting include prompt reporting of suspected unexpected serious adverse events or reaction.

3.5 KBTH responsibilities

This is the organization hosting the study and KBTH employee may be involved in conducting the study.

Key responsibilities of KBTH:

- Promoting a quality research culture
- Ensuring researchers understand and discharge their responsibilities
- Ensuring studies are properly designed and submitted for independent review
- Ensuring studies managed, monitored and reported as agreed according to the protocol
- Giving permission for research involving their patients, service users, care providers or staff before the research starts
- Ensuring research is conducted to the standards set out in this documents
- Taking action if misconduct or fraud is suspected
- Retaining responsibility for the care of participants to whom KBTH has a duty
- Promoting the dissemination of research findings and their use in enhancing service delivery

3.6 Korle-Bu Teaching Hospital Institutional Review Board (KBTH-IRB)

Committee established to provide participant researchers funders sponsors employers care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognized ethical and scientific standards

Key responsibilities of the IRB (details are available from the KBTH IRB SOP'S):

- Provide ethical and scientific review for research
- The KBTH-IRB is responsible for reviewing their advice on the ethical acceptability of a study in the light of any new information.

3.7 Monitoring and Ensuring Compliance

Arrangements will be made to work with and through structures that already exist or being developed in KBTH, the Ministry of Health, Ghana health service and other institutions to promote and monitor research quality. KBTH'S researchers are expected to be able to

- Demonstrate adherence to this document.
 - i. Reassure patient's, service users, care providers and professionals of the quality of KBTHS services.
 - ii. Reassure KBTH reputation in high quality research and care.

Failure of KBTH or employees of KBTH to comply with this document will be addressed through the Normal line of accountability and performance management. It is the responsibility of other organizations working with KBTH to have appropriate systems to address failure by their staff.

The R & D in consultation with other relevant persons will be responsible for creating an assessment framework including reviews and inspections of KBTH sponsored research projects.

The KBTH IRB is however mandated to monitor all projects in general.

3.8 Misconduct

In case of misconduct, professionals are subject to disciplinary action by KBTH's disciplinary committee and their professional bodies where applicable. Irrespective of the ruling by a professional body, KBTH shall subject researchers to any stipulated measures put in place to address misconduct.

The KBTH IRB may withdraw ethical approval in cases of research misconduct.

Chapter 4 GUIDANCE FRAMEWORK

4.1 Introduction

The conduct of research related to healthcare is subject to a wide range of national and international guidance, guidelines, declarations and regulations (which we will call guidance in this policy document). The international guidance has formed the basis for the national guidance adopted in many countries. In general, the guidance covers a wide range of activities in research involving human participants.

Four main principles guide decision-making in the conduct of research related to healthcare in developing countries:

- The duty to alleviate suffering
- The duty to show respect for persons,
- The duty to be sensitive to cultural differences
- The duty not to exploit the vulnerable

These principles are reflected in the various forms of guidance but are sometimes expressed in different ways. For example, respect for persons is sometimes expressed more narrowly as respect for individual autonomy. The duty to alleviate suffering is sometimes referred to in terms of beneficence, or a duty to benefit other people, and the duty not to exploit the vulnerable encompasses guidance expressed in terms of fairness and justice.

In addition, two common themes arise in the various forms of guidance. The first is the need for research to be based on sound scientific principles, on knowledge derived from laboratory and animal experiments, if appropriate, and on a sound understanding of the scientific literature. The second is the need to ensure that the results of research are accurately reported and published, that publication can only take place where it can be demonstrated that ethical principles relevant to the conduct of research have been observed, and that negative as well as positive results are reported.

4.2 The historical context

Over the last few years, unethical clinical research has resulted in the ill treatment of participants. The Nuremberg Code was formulated in 1947 following the Nuremberg trials. The central feature of the Nuremberg Code was the protection of the integrity of the person participating in research. The Nuremberg Code was endorsed by the World Medical Association (WMA), which published the Declaration of Helsinki in 1964. The Declaration, which has been revised several times, sets out the principles to be observed in research on human participants and has become the cornerstone of research related to healthcare. Its standing is such that the principles enshrined in it have been incorporated into many of the forms of guidance that have subsequently been drawn up to govern the conduct of research related to healthcare (see Table 1).

Table 1. Historical chart for the conduct of research related to health care.

Year	Organization	Title
1947	War crimes tribunal at Nuremberg	Nuremberg code
1948	United Nations General Assembly	Universal Declaration of human rights
1964	World Medical Association (WMA)	Declaration of Helsinki (DOH) [1]
1975	WMA	DOH [2] Tokyo
1983	WMA	DOH [3] Venice
1989	WMA	DOH [4] Hong Kong
1991	CIOMS*/WHO	International Guidelines for ethical review of epidemiological studies
1993	CIOMS/WHO	International Ethical Guidelines for Biomedical Research Involving Human Subjects (Under revision in 2001–2)
1995	WHO	Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products
1996	WMA	Declaration of Helsinki [5] South Africa
1996	Tripartite International Conference on Harmonization	Good Clinical Practice (GCP)
1997	UNESCO	Universal Declaration on the Human Genome and Human Rights
2000	UNAIDS	Ethical Considerations in HIV Preventive Vaccine Research
2000	WHO	Operational Guidelines for Ethics Committees that Review Biomedical Research
2000	WMA	Declaration of Helsinki [6] Edinburgh

*Council for International Organization of Medical Sciences

According to the Edinburgh version (2000) of the Declaration, any research carried out involving human participants must be based upon sound scientific principles, and according to a properly formulated protocol for the study that has been subjected to the scrutiny and advice of an independent committee (i.e. a research ethics committee or an institutional review board). The Declaration recognizes the fact that most interventions – diagnostic, therapeutic and preventative – and especially those involving biomedical research, involve hazards and that the issues of risk and hazard must be addressed. It notes that when research involves healthy volunteers, special care must be taken to determine if the objective of the research outweighs the inherent risks and burdens to participants. The Declaration pays particular attention to the problems that may arise where research is combined with professional care. The Declaration states that the hazards attendant upon the project must be predictable and where they outweigh the potential benefits, the research should not proceed. In carrying out such an assessment, the interests of the subject must always prevail over the interests of science, industry, or society.

4.3 Importance of Good Clinical Practice (GCP)

GCP is an international ethical and scientific quality standard for the design Conduct and record of research involving humans.

Comprising 13 core principles, GCP applies to all clinical investigation that could affect the safety and wellbeing of human participants (in particular, clinical trials of medical products and medical devices).

GCP was developed by the (regularly) regulatory authorities of the EU, Japan and US in a steering group termed the Tripartite International Conference on Harmonization (ICH) and provide international assurance that:

- Data and reported results of clinical investigation are credible and accurate, and protected.
- Right, safety and confidentiality of participants in clinical research are respected and protected.

GCP was finalized in 1996 and became effective in 1997. When first expounded, it was an internationally recognized simply as recommended as best practice, but is now enforceable by law in some countries.

4.4 The 13 Basic GCP Principles

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement (s).

2. Before a trial is initiated, foreseeable risks and inconvenience should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available non- clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (KBTH IRB) independent ethics committee (IEC) approval /favorable opinion.
7. The medical care given to, and medical decision made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement (s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable Good Manufacture practice (GMP). They should be used in accordance with the approved protocol.
13. System with procedures that assure the quality of every aspect of the trial should be implemented.

KBTH expects all researchers to abide by the Good Clinical Practice Consolidated Guidelines (ICH-E6)^a

Chapter 5 DATA PROTECTION GUIDELINES

5.1 Introduction

Researchers must ensure that research patients' dignity and interest are paramount. According to the Patient Charter in the Public Health Act, Act 851, the patient is entitled to confidentiality with regards to the patient's information and that no third party shall be provided with a patient's information without the patient's consent or whoever is acting on the patient's behalf when the information is required by law or is in the public interest. Researchers will be required to be cognisant of this provision.

Research involving personal data in any form carried out in KBTH must be:

- i. Processed via the KBTH IRB
- ii. Processed for clearly specified purpose
- iii. Adequate, relevant and not excessive for the purpose

The researcher must ensure that data generated is:

- Accurate
- Secure (accessible by only authority persons)
- Kept no longer than stipulated
- Processed in accordance with exiting data protection laws in Ghana
- Only transferred to countries with adequate data protection system following a signed agreement.

5.2 Some Important Terms related to data

Personal information: all information about individual, living or dead. For example medical records which are written or held on a computer system, images, recordings, information obtained from samples and opinions expressed about the individual.

Personal data: it is information about living people which in isolation or in combination with other data which may be available, may lead to the identification of the patient.

Confidential Information: in the context of healthcare, is information about oneself given on the explicit or implicit understanding that it will not be disclosed to others outside the patient's care without the patients' consent. It is assumed that this is the case when personal information is disclosed as part of clinical care.

Sensitive Information: refers to information about individual which may have particularly deleterious effect if it is disclosed inappropriately, this includes all information about physical or mental health or condition, or sexual life.

Coded Data: this is not anonymous data. Identities are disguised by the code but the code can be easily decoded by those in control of the data. For example, an ‘ alphanumeric code’ made up of a patient’s postcode/ initials for the situation (except in exceptional situations where the need is waived by KBTH).

Anonymised data: is data which has been coded by other outside the research team, for example from a National Database such as the Ghana Statistical Services or a large pharmaceutical company. Permission for this data to be used in future research should be requested at the time of initial consent to registration or research.

Linked Anonymised data: can be decoded by the organization supplying it to the researchers but not by the researchers themselves. For example, KBTH may need to link perhaps unexpected research data to a particular patient in the interests of their care. Informed consent from patient is sometime necessary when using linked anonymous data. The KBTH IRB should be consulted.

Unlinked Anonymised data: describe the situation where the link between the data and the person to whom it refers has been irreversible broken. No one could use this data to identify a specific individual. Informed consent is usually not necessary for research which makes use of unlinked Anonymised data.

5.3 Use of Existing Data Sets Including Stored Samples

Research work that makes use of existing data sets (and stored samples) must follow what KBTH refers to as the modified Caldecott principles. The R & D will be responsible for ensuring that these principles are respected and acted upon.

The Caldecott principles are as follows:

Principle 1- justify the purpose (s): every proposed use or transfer of patients- identifiable information within or from an organization should be clearly defined and scrutinized, with continuing uses regularly reviewed by the KBTH IRB.

Principles 2- don’t use patient-identifiable information unless it is absolutely necessary: patient-identifiable information items should not be used unless there is no alternative.

Principle 3- use the minimum necessary patient-identifiable information: where use of patient-identifiable information is considered to be essential, each individual item of information should be justified with the aim of reducing identifiably.

Principle 4- access to patient- identifiable information should be on a strict need to know basis:

Only those individual who need access to patient-identifiable information should have access to it, and they should only have access to the information item that they need to see.

5.4 Important General Guidelines to Researchers

- Where informed consent is not possible, justify this in detail to the KBTH- IRB.
- Contact the R&D office for assistance with data protection in line with this guideline and the approved protocol.
- Access to patient's record must be limited to only the researchers and other staff who might have need of it for a particular purpose. Patients involved should have specifically consented to this. Patient data cannot be accessed or shared without the consent of the patients.
- Store all non-electronic research data in locked filing cabinets (including cassette tapes, CD and video recordings) and ensure that this is accessible only to authorized persons.
- Make sure that sponsors (who have access to the data) do not remove it to another country without appropriate authorization and adequate data protection systems spelt out in the approved protocol.
- Remember that the ‘ ‘ funders’ ’ have no right to check patients records on which research is based unless they have taken on formal responsibility as ‘ ‘ sponsors’ ’ of research.
- Non staff of KBTH or UG wanting to access data, samples or patients for research must receive the relevant permission from KBTH's management through the Director of Medical Affairs.
- Non staff performing any responsibilities regulated by existing professional bodies in Ghana must obtain the requisite license.
- The principal or lead investigator is responsible for ensuring the appropriate archiving of data when the research has finished.
- All unwanted documentation/ paper which contains confidential data must be shred/ torn up rather than simply thrown into the bin- this includes study protocol etc. however, all documentation/ data connected with the study should be kept for the minimum term stated depending on the kind of research (usually five years) in a secure environment.