CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF STUDY

Research is discovery of new facts, enunciation of new principles, or fresh interpretation of the facts or principles. It is a systematic Investigation to develop or contribute to generalizable knowledge[1]. Research it is systemic and organized wayof finding better answers to questions. It is a step in searching for truth and the basic function of research is to answer why and how of a phenomenon. It also involve searching answers to what, when, how much, etc. All thesequestions have relevance to any discipline but Medicine seems tohave special appetite for such enquiries. The goal of medical researchis to improve health, and the purpose is to learn how systems in human body work, why we get sick, and how to get back to health and stay fit.It is a systematic process to better determine ethology, patho-physiology, diagnosis, therapy and prognosis. Research is the very foundation of improved medical care[1].

The Nazi physicians conducted harmful research on unwilling human subjects during World War II and were unprecedented in their scope and the degree of harm and Suffering to which human beings were subjected "Medical experiments" were performed on thousands of concentration camp prisoners and included deadly studies andtortures such as injecting people with Gasoline and live viruses, immersing people in ice water, and forcing people to ingestpoisons[2].

The rights of the subjects were violated by physicians. The actions were condemned as crimes against humanity. Permissible Medical Experiments were to be carried out and this becameknown as theNuremberg Codeand was the first international code of researchethics. The code stated the basic principles that must be observed in order to satisfy moral, ethical, and legal concepts in the conduct of human subject research[2].

The approach of patient participation in medical decision- making has been discussed openly in Germany. However, the first publications in German[3]only discussed the approach conceptually. Clinical trials fortheevaluation of patient participation in medical Decision making were primarily initiated through the research program of theFederal Ministry of Health[4].

In 1999, theConference of German Health Ministers adopted the document''Patient rights in Germany today''. It is explicitly laid down that patients have the right to clear, expert and satisfactory education and counselling in order to explain the usage and risks of diagnostics, and advantages and risks of the treatment or non-treatment options. Physicians must be sure that patients have understood the information. It is pre-assigned that patients must be informed about the type and Possibility of different risks and their relation to recovery chances[3].

Randomized controlled clinical trials are the most rigorous way to determine treatment efficacy.Recruitment into clinical trials, however, is notoriously difficult in general[5], and surgical trials in particular face further obstacles to recruitment [6]. Low recruitment leads to poor statistical power to detect meaningful differences, subjecting participants to potentially risky interventions with no guarantee that their participation will lead to results of scientific value[7]. Investigators planning a Randomized controlled clinical trial mustensure that recruitment of subjects intothetrialwill be sufficient to achieve the study aims.

In addressing issues of trial recruitment, investigators have tried to Identify barriers to clinician andpatient participation[8], to modify trialsto make them more palatable to clinicians and patients [9]and to assess differences between those patients who agree to participate in trialsand those who refuse[10].

Demographic factors, such as gender, race, age and education level, have been associated in some studies with willingness to participate[5].

1.2.PROBLEM STATEMENT

Research withhuman subjects can occasionally result in a dilemma for investigators. When the goals of the research are designed to make major contributions to a field, such asimprovingthe understanding of a disease process or determining the efficacy of an intervention, investigators may perceive the outcomes of their studies to be more important than providing protections for individual participants in the research[2].
Although it is understandable to focus on goals, our society values the rights and welfare of individuals. It is not considered ethical behaviour to use individuals solely as means to an end**.** The importance of demonstrating respect for research participants is reflected in the principles used to define ethical research and the regulations, policies, and guidance that describe the implementation of thoseprinciples[2].us
It is becoming increasingly recognised that patients can make Valuable contributions to their health care safety[11]. However, while these interventions are well intentioned, a key issue is the lack of evidence on patients' preferences to adhere to the advice and recommendations, namely how willing patients really are to take on such an active role[12]. Patients were more willing to ask factual (eg, 'How long will I be in hospital for?')as opposed to challenging questions(eghave you washed your hands?') particularly when interacting with a doctor .The research also highlighted the potential facilitating role of doctors: patients reported they would be more willing to ask challenging questions if they were instructed to by a doctor.In addition, previous research solely examined the potential effect that doctors could have on increasing patients' willingness to participate. However, given patient involvement in safety is largely a function of patients' interactions with different health care professionals[12].

1.3 JUSTIFICATION

Available studies have showed that patients value safety, convenience, oversight and open communication in research. However they were put off by some aspects that are valued by health care professionals. Educating the public about research may improve participation.
This study was conducted in order to evaluate factors that will improve Patients' willingness to participate in research and to assess patients' awareness of medical research. Also to educate and encourage patients that they are essential to the conduct of research intended to improve human health in UBTH. As such,the relationship between investigators and human subjects is critical and should be based on honesty, trust andrespect.

EVALUATION OF PATIENTS' WILLINGNESS TO PARTICIPATE IN MEDICAL RESEARCH IN UBTH AND CENTRAL HOSPITAL; A COMPARATIVE STUDY