CONDUCT OF ETHICAL RESEARCH: PERCEPTIONS, BARRIERS AND MOTIVATORS IN A HEALTH RESEARCH COMMUNITY IN NIGERIA

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ABSTRACT

INTRODUCTION. There is increasing concern globally that ethical standards in research, including health research, are low, worsened by inadequate training in research ethics in developing countries like Nigeria. The objectives of this study, therefore, were to determine health researchers' level of awareness of the requirements for research to be ethical; to describe their pattern of practice of research misconduct; and to identify the motivators and barriers of ethical conduct of health research. The findings of this study would provide evidence and baselines for appropriate interventions to promote ethics in health research in Nigeria.

METHODOLOGY. A descriptive cross-sectional multi-centre design was used. The study participants consisted of 109 lecturers in the clinical departments in accredited university medical schools and consultants in their corresponding teaching hospitals in Edo and Delta States of Nigeria. With the aid of self-administered, structured questionnaires, data were collected on respondents' knowledge of requirements for the ethical conduct of research, their previous training in research ethics, their personal research misconduct and perceived barriers and motivators to ethical conduct of research. Analyses, including X^2 tests and logistic regression, were done to determine possible associations and explanatory or predictor variables.

RESULTS. Informed consent and respect for participants were the best known requirements for research to be ethical, each having a correct response of 96.2%. Of the 100 respondents who had been trained on research ethics, 39 (39.0%) knew all the itemised requirements for ethical research compared to 11 (33.3%) of the 33 who had not been trained. This difference was not statistically significant ($p=0.560>0.05$). Among the major research misconducts (fabrication, falsification and plagiarism) the most frequently committed was fabrication, 19 (15.7%), and this was the second most commonly committed of all types of the itemised misconducts. The most frequently committed research misconduct overall was inadequate record keeping, 39 (30.5%). The most frequently stated barriers were the lack of funds, 95 (74.8%), lack of facilities, 93 (72.7%), inadequate training in research ethics, 57 (45.6%) and inadequate training in research methods, 58 (45.3%). Provision of training for research methods and research ethics, 122 (95.31%) and funding for research, 119 (93.0%) were the major motivators. Among the other motivators, the provision of facilities and physical space was the major one stated. Respondents who were trained in research ethics did not know ethical requirements for research better than those who were not. But the knowledge of these requirements was shown to be explanatory to the non-committal of an ethical misconduct. Again, those who indicated inadequate knowledge of research ethics and research methods and who had not been trained in research ethics were, in their separate categories, more likely to have committed at least one of the itemised research misconducts. These associations were statistically significant ($p<0.05$).

CONCLUSION. These findings reveal the pattern and associated factors of health research misconduct in a Nigerian environment and point to the need for a comprehensive programme for training in research ethics and research methods and to promote best ethical practices in the conduct of health research.

Key words: research misconduct; ethical requirement; health research; research ethics training; Nigerian universities

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DECLARATION

I hereby declare that this work is original unless otherwise acknowledged. This work has not been presented or submitted elsewhere for the award of a degree or for publication.

Dr. Omokhoa A. Adeleye

CERTIFICATION BY SUPERVISOR

I certify that the materials recorded in this thesis resulted from research carried out by Dr. Omokhoa A. Adeleye of the Department of Surgery, Faculty of Clinical Sciences, College of Medicine, University of Ibadan, Ibadan, Nigeria, under my supervision.

Supervisor

TABLE OF CONTENTS

Title page	
Abstract	iii
Acknowledgement	v
Declaration	vi
Certification by supervisor	vii
Table of contents	viii
Introduction	1
Literature Review	6
Methodology	12
Results	19
Discussion	28
Conclusion	37

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CHAPTER ONE

INTRODUCTION

A major issue frequently discussed in the research and ethics communities is the need to promote best ethical practices in health research. Such attention is justified on the grounds that health research carries the potential of harm to human participants. Again, health-related decisions are often research-dependent and research that is not ethically conducted is likely to yield misleading results. While a lot is known about moral theories and principles generally, some gaps still exist in ethical research practice. This is traceable to wide knowledge and training gaps among many researchers in those principles applicable to research, especially in developing countries. Fortunately, there is a gradual build-up of resources in research ethics in developing countries, including Nigeria. This has informed empirical studies that will hopefully provide a basis for the sustained promotion of ethical conduct of research in the country.

A twofold theoretical premise guides this thesis. First, there is the consideration of what makes research ethical, that is, what specific features should be sought in research for it to be said to be ethical. The second consideration is what makes research *not* ethical, or, conceptually, what constitutes research misconduct which should therefore be absent from ethically conducted research.

In line with Beauchamp and Childress' thoughts, four principles are now widely held in modern bioethical parlance as aggregating the elements of biomedical research ethics (also applicable in clinical ethics) – respect for autonomy, beneficence, non-maleficence and justice.[1] Over the years, these principles have been elaborated to form elements or criteria for deciding on and analysing the ethicality of a research work. For example, the International Ethical Guidelines for Biomedical Research Involving Human Subjects, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO), sometimes called 'the CIOMS guidelines,' contains specific criteria such as informed consent, confidentiality, compensation, the need for ethical review, etc.[2] Nigeria's National Code of Health Research Ethics contains similar criteria for assessing the ethicality of a proposed or conducted research.[3]

The second component of the theoretical framework addresses research misconduct, an antithesis of ethical research. This consideration enables the direct identification of unethical practices in biomedical research and, therefore, conducts that must be excluded from research in order to merit its being described as ethical. The United States White House National Science and Technology Council (Office of Science and Technology Policy) defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results." Other types of misconduct (e.g., stealing, intimidation and discrimination) are left to be tackled through other official regulatory mechanisms.[4]

There have been concerns about how to clearly define research as different from other activities that involve some form of scientific observation or enquiry. One of the sources of concern is that the term "research ethics" suggests that ethical requirements are exclusively applicable to research. The World Health Organisation Research Ethics Review Committee (WHO-ERC) defines research involving human participants as "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records."[5] Research has also been defined in the CIOMS guidelines as "a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context 'research' includes both medical and behavioural studies pertaining to human health." It is this latter contextual definition that is adopted for the purpose of this thesis.

THE RESEARCH PROBLEM

The need to be ethical in the applications of ethical principles in research has been of increasing concern for about half a century. Formal and structured systems in technologically advanced countries have been evolving with time for the teaching and practice of ethics in research, using uniform standards. The pace has been much slower in developing countries, leaving much gap to be filled.

Concomitantly, the Millennium Development Goals (MDGs) have put challenges before many developing countries, including Nigeria. Three of the eight goals, eight of the sixteen targets and eighteen of the forty-eight indicators are directly health-related. Health research, being one of the key drivers towards the attainment of these objectives, is being encouraged from within and outside the country.[6] Of course, high ethical standards that support the validity of the conduct and findings of health research are required to provide evidence for consequent practice.

With possible and expected increase in research activities comes an increase in the need for researchers to be motivated towards improved ethical practices in line with current global trends. Otherwise, there is the risk of a simultaneous increase in the risk of conducting research unethically. Apart from these, the increasing demand for research also increases the need for researchers to improve on scientific skills, since the compromise of scientific validity in research is unethical.

Where some knowledge of research ethics exists in developing countries, empirical studies to identify areas of strength and weakness and their determinants are few. In particular, studies have not addressed researchers' perception of what constitutes ethical research and research misconduct. Much is also yet to be known of the barriers and motivation for ethical practice in research.

JUSTIFICATION

Studies on the perception, barriers and motivation in a health community will generate data that can be useful for planning appropriate interventions. They will also be useful in monitoring and evaluating on-going research activities in such a way that priorities can be addressed with time. Such interventions will, expectedly, include improved training and practice in research methods and research ethics in the health sciences. Since empirical research in research ethics is still relatively in its infancy especially in developing countries including Nigeria, this study will not only add to the growing body of knowledge in the subject but will be available for possible replication and further improvement of its methodology. The study findings, including improvements in research skills, especially with ethical inputs, will potentially influence policy thrusts that will add value to development efforts both within and outside the conventional health sector.

OBJECTIVES

General Objective

The general objective is to understand researchers' perceptions, barriers and motivators of ethical conduct of research in a health research community.

Specific Objectives

1. To determine the researchers' level of awareness of the requirements for research to be ethical
2. To describe the pattern of practice of research misconduct by respondents and other researchers known to them
3. To identify the motivators and barriers of ethical conduct of health research

CHAPTER TWO

LITERATURE REVIEW

The subject of research ethics and the challenge of conducting research ethically have gained increasing attention in the research community globally. This appears to have been in response to historical antecedents and contemporary trends of unethical research practices that have tended to cast health research and researchers in bad light, given the harm caused to human participants.

For example, during the World War II (1939 – 1945), biomedical researchers, including physicians, carried out highly injurious procedures on non-consenting war prisoners, subjecting them to mutilations, severe pain, extreme suffering, deformities and death. The Nuremberg Code[7] was a part of the 1947 judicial rulings in the trials that followed.

Over time, concerns grew towards the broadening of issues that should be considered as ethical or unethical conduct in research involving human participants. There have been progressive attempts to extend these beyond the regulations provided for in the Nuremberg Code. For instance, observing, among others, that there was the need for physicians to give due consideration to the superiority of benefits above risks in medical research and for independent review of proposed research as ethical requirements, the Declaration of Helsinki was developed by the World Medical Association in 1964.[8]

The United States Public Health Service Syphilis Study (1932-1971), commonly known as the Tuskegee study, was commenced before, and continued during and after the Nazi World War II experiments. The study objective was to observe and document the natural history of syphilis in African-American men, to see if these findings would differ from those previously made on whites. Six hundred disadvantaged, rural black patients were enrolled, of whom 400 had latent syphilis, and the 200 who did not, served as controls. The men were enrolled for the study never knew that they were study subjects. These unethical practices of biomedical researchers occurred despite the Nuremberg Code and the Declaration of Helsinki. Nevertheless, one response to this and similar studies in the United States at the time was to develop principles to guide the formation of specific rules and regulations governing research on human participants with unique emphasis on ensuring that vulnerable individuals and populations are not targeted for high-risk research. These are expressed in the Belmont Report, released in 1979.[9]

Thus, acts by biomedical researchers that were considered to be unfair, immoral or unduly exploitative of research participants and therefore unethical served as triggers for foundational guidelines in research ethics. The aim was largely to forestall similar and related occurrences.

As indicated in the introduction, the theoretical framework for this thesis derives from the definitions of what constitutes ethical research on one hand and unethical research (or research misconduct) on the other hand.

As regards what constitutes ethical research, the basic philosophies underlying major ethical codes and relevant documents have been useful. Drawing from these, Ezekiel Emmanuel and his colleagues proposed seven requirements that aid the systematic and coherent evaluation of the ethics of clinical research. They include "value— enhancements of health or knowledge must be derived from the research; scientific validity—the research must be methodologically rigorous; fair subject selection—scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; favourable risk-benefit ratio—within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; independent review—unaffiliated individuals must review the research and approve, amend, or terminate it; informed consent—individuals should be informed about the research and provide their voluntary consent; and respect for enrolled subjects—subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored." Ezekiel Emmanuel and his colleagues opined that implementing these requirements was necessary and sufficient to make clinical research ethical.[10] These requirements appear to be comprehensive and yet operable as a practical guide that can inform the practice of ethical research from local institutional to international levels.

As mentioned in the preceding chapter, the United States Federal Misconduct Policy (under the authority of the OSTP) defines research misconduct as fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results."[4] This policy permits the specification of minimum standards for measuring, rather than a universal standard for judging acceptable research behaviour. That way, the US government is able to address "well-documented, serious departures from accepted research practices," that is, FFP.[11] This clarification is important because it implies that, while FFP may be seen as major or serious form of misconduct, they should not be seen synonymous with "research misconduct."

It is in this light that one considers the term “questionable research practices” as different from “research misconduct.” Examples of these include misinterpretation of credential, conflicts of interest that impact results or actions, undeserving or improper authorship and sloppy and bias publication practices. Both terms constitute deviations from responsible conduct of research.[12]

But The Wellcome Trust, Britain's largest biomedical charity, provides a rather all-encompassing, comprehensive definition of research misconduct as: “fabrication, falsification, plagiarism or deception in proposing, carrying out, or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates, or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It also includes intentional, unauthorized use, disclosure, or removal of or damage to research related property of another including apparatus, materials, writings, data, hardware or software or any other substances or devices used in the conduct of research. It does not include honest error or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results or misconduct unrelated to the research process. Similarly, it does not include poor research unless this encompasses the intention to deceive.”[13] It can be seen from the foregoing that ethical issues in the conduct of research cover the full range of activities from conception to publication. Indeed, recent empirical studies point to a widening range of practices that may be included in the practical definition of research misbehaviour.

The major part of scientific literature on the subject of research ethics is based on opinions and analyses of events. Empirical research on the subject is relatively sparse and still in its infancy globally. The recency of empirical studies on personal research misconduct is illustrated by Geggie's finding of only two articles in this subject when he did a 'medline' search in preparation for his study published in 2001.[14] The first article he found was a pilot study of United States-based biomedical trainees' perceptions concerning research ethics in which 15.1% of them admitted personal instances of misconduct.[15] The second was a Norwegian study of academic medical researchers which reported that 18.0% of respondents agreed fully or in part that they had been exposed to scientific misconduct.[16] Geggie's study may be one of the first empirical studies published in this field in this century. His study, conducted on newly appointed (not necessarily newly qualified) medical consultants, showed that 55.7% of them had observed some form of research misconduct, 5.7% admitted to past personal misconduct, 18.0% were either willing to commit or were unsure about possible future research misconduct and only 17.0% reported having received any training in research ethics.[14] All these studies point to the enormity of the problem of research misconduct and that some researchers are not averse to continuing research misconduct. These further justify the need to continue to conduct similar studies in different research environments in the hope that appropriate interventions can be developed.

More recently, Martinson and his colleagues conducted a large survey on researchers funded by the National Institutes of Health in the United States. They identified the following as the most serious forms of misbehaviour among researchers - falsification/fabrication, ignoring major aspects of human subject requirements and not properly disclosing involvement in firms whose products are based on one's own research. But the commonest self-reported events were inadequate record keeping related to research projects, dropping observations or data points from analyses based on a "gut feeling" that they were inaccurate and using inadequate or inappropriate research designs.[17]

Some investigators have studied personal knowledge of research misconduct committed by others. In a national survey of coordinators and managers of clinical research studies in the United States, 18.3% of respondents indicated first-hand knowledge of an actual occurrence of misconduct within the previous year. Respondents based in institutional settings identified as academic medical centre were more likely to indicate first-hand knowledge of an incident compared to other settings combined. Practices perceived as occurring most often included protocol violations related to subject procedures (43%) or enrolment (36%).[18] These obviously violate the principle of respect for persons and may reflect the ease with which and the extent to which some researchers may be willing take advantage of research participants. It must be kept in mind that while percentages of personal knowledge of research misconduct may be important in demonstrating the extent to which research misconduct is known, they do not directly measure the burden of the problem as data on the personal misconduct do.

Identifying researchers' knowledge and practices regarding research ethics and research misconduct and exploring their challenges in this regard will hopefully facilitate the development of appropriate interventions to promote ethical research and eliminate research misconduct. Such interventions would be worthy actions because they are vital for the safety of mankind and for the pursuit of development. It is for this reason that this study was conducted.

CHAPTER THREE

METHODOLOGY

STUDY SITES AND STUDY POPULATION

The study was conducted in Edo and Delta States in the current South-South geopolitical zone of the country. The two states constituted the old Midwestern state in Nigeria. The study sites were the medical schools of the universities and the corresponding teaching hospitals in the aforementioned states. These were the University of Benin (UNIBEN)/ University of Benin Teaching Hospital (UBTH), Benin City, Ambrose Alli University Ekpoma, (AAU)/ Irrua Specialist Teaching Hospital, Irrua (ISTH), and Delta State University (DELSU), Abraka/ Specialist Hospital, Warri.

To qualify as medical schools, accreditation is required with the Medical and Dental Council of Nigeria (MDCN) and the Nigerian Universities Commission (NUC). These bodies use criteria including qualifications of lecturers, research capacities of institutions and a standard teaching hospital in adjudging a medical school as fit for accreditation. Teaching hospitals are set up for teaching, research and patient care. The current minimum qualification for appointment as a lecturer is a Fellowship or PhD, although a Masters degree is occasionally accepted with an MBBS (bachelor of medicine, bachelor of surgery) or BDS (bachelor of dental surgery) degree in the absence of personnel with higher qualifications in fields like pharmacology and the sciences of pathology. To be a teaching hospital consultant, a Fellowship along with MBBS or BDS is invariably required. Lecturers with the required qualifications in the universities are often the ones that double as consultants in the teaching hospitals (and sometimes, vice versa). Thus, the conduct of studies involving human participants is commonplace in accredited medical schools and their accompanying teaching hospitals. To qualify for promotion, lecturers are required to have conducted and published specified numbers of studies. Promotion criteria are similar in all the institutions up to the level of a Senior Lecturer, but differ widely for higher levels. Teaching hospital consultants who hold this as their primary employment conduct research and supervise Fellowship theses, but these are not required for their promotion.

STUDY DESIGN

The study was a descriptive cross-sectional multi-centre design. All the study participants responded to interview questions in one phase using self-administered, structured questionnaires as interview tools.

STUDY PARTICIPANTS

The study participants consisted of lecturers in accredited university medical schools and consultants in their corresponding teaching/specialist hospital departments. Only lecturers and consultants in Microbiology, Haematology, Chemical Pathology, Morbid Anatomy, Pharmacology, Surgery, Medicine, Child Health, Obstetrics and Gynaecology, Psychiatry and Community Medicine were considered as having sufficient scope of practice and research involving human participants for the purpose of this study. The aforementioned institutions were those that had been accredited as stated. However, Igbinedion University, Okada (IUO) was excluded because it had no accredited teaching hospital and the hospital used instead is not considered to have research culture. (The very few lecturers in the university's primary employment were engaged as participants in the pre-test for this thesis.) A similar situation exists with Uselu Psychiatric Hospital, Benin City, which is not a university teaching hospital and is considered not to have sufficient research content in its activities. In the case of DELSU (which was included), the participants were primarily lecturers in the partially accredited medical school, and had started developing a research culture including journal publications, etc, as normal requirements for their promotion.

SELECTION CRITERIA

Inclusion criterion. All lecturers in accredited university medical schools and consultants in their corresponding teaching/specialist hospital departments were enrolled following consent to participate in the study.

Exclusion criterion. Non-consenting researchers among those who otherwise met the inclusion criteria were excluded.

SAMPLE SIZE

Martinson et al reported that, overall, 33% of their respondents said that they had engaged in at least one of the top ten (judged to be most serious) misconducts in their study. They adjudged themselves to be the "first to provide empirical evidence based on self reports from large and representative samples of US scientists that document the occurrence of a broad range of misbehaviours."[17] No similar study on self-reported misconduct is known to have been done in Africa. It was estimated that the value may be about 15% higher, that is, 48%.

The sample size estimation for the one-sample binomial test (two-sided alternative) was used. Thus,

$$n = \frac{p_0 q_0 \left[Z_{1-\alpha/2} + Z_{1-\beta} \sqrt{\frac{p_1 q_1}{p_0 q_0}} \right]^2}{(p_1 - p_0)^2}$$

Where

n is the minimum sample size required for the study

p_o is the proportion in the population; taken to be 33% from the above study,

p_1 is the alternative proportion, estimated to be 48%

$Z_{1-\alpha/2}$ is the Z value at an α value of 0.05, and

1-β is the power of the study, put at 90%

Computing for n, n = 109

Therefore, at least 109 participants were enrolled for the study.

The total number of potential participants who met the inclusion criterion and were expected to give consent was estimated to be about 150.

ETHICAL CONSIDERATIONS

Ethical Approval. Ethical approval for the study was granted by the Research Ethics Committee (REC) of UBTH.

Assent. Assent to conduct the study was obtained from the heads of the institutions, the respective departments and relevant associations to which the potential participants belonged. As entry points, their cooperation and assistance to access potential participants was obtained. This helped to facilitate individual consent to participate.

Informed Consent and Assurance of Confidentiality. Each participant was informed on the nature and purpose of the study. Individual identifiers such as name and signature were not required as part of questionnaire data. In addition, assurance was given to the participants that confidential information about them that became known to the investigator or research assistant would be handled with strict confidentiality. To further assure confidentiality, the questionnaires were self-administered and returned, upon completion, into a common receptacle at each study site. The enrolees were also informed that their voluntary agreement to answer the survey questions constituted informed consent. This information was placed as an introductory part of the questionnaire.

Vulnerability. The participants were not under any form of supervision or oversight of the investigator and did not owe him any form of official allegiance. This situation did not change throughout the period of the study.

Benefits. Enrolees are expected to consent to participation for altruistic reasons. However, an incentive that doubled as a benefit was to enable them to build or strengthen their knowledge base in research ethics by facilitating their entry into the Collaborative Institutional Training Initiative (CITI) programme under the auspices of West African Bioethics programme. Each respondent was also be offered a copy each of the National Code of Health Research Ethics and the 'the CIOMS guidelines,' (both in a compact disc) after all questionnaires were returned. The timing was to forestall access to and sharing of information from the resources, so as not to influence responses. Institutions were also offered the benefit of honorarium-free training workshops on research ethics after data collection.

PRETEST

The questionnaire was pre-tested among lecturers in the College of Health Sciences, Igbinedion University, Okada. The pre-test findings, which were not parts of the report of this thesis, provided opportunities for amendments to the questionnaire before administration.

DATA MANAGEMENT

Data Collection. Data was collected with the aid of semi-structured self-administered questionnaires containing open-ended and closed-ended questions covering basic demographics and variables derived from the study objectives. A sample of the questionnaire used is in the appendix. Lecturers were implored and trained as research assistants who helped to track other participants for questionnaire administration and retrieval. This was required to facilitate a high response rate.

Data Collation. Data was collated into a Stata/SE 10.0 for Windows (Stata 10) in which the analysis was also done.[19]

Data Presentation. Data, such as those on basic demographic characteristics and selected variables, were presented using simple frequency and contingency tables. Analysed data were also presented as cross-tables and annotated logistic regression tables to show the main output features (see below). A pie chart was used to present categorical data.

Data Analysis. Analysis was done to demonstrate contents and patterns of experiences, perceptions, barriers and motivators with respect to ethical conduct of research. Logistic regression and the χ^2 test were the major analyses done. The level of significance, α, was 0.05. Odds ratios (OR) were computed with their 95% confidence limits.

STUDY LIMITATION

The study design allowed for only conservative estimates of research misconduct because of non-response bias. This arose from the likelihood that those potential participants who had been more involved in research misconduct may have decided not to participate in the study or to withhold response to the relevant questions as was found in some instances. Untrue responses may also occur among respondents for the same reasons.

As discussed in the Literature Review, FFP constitute “serious departures from accepted research practices.” In this study, they have thus been termed “major research misconducts.” This by no means implies that other forms of research misconduct – such as publishing the same data or results in two or more publications and manipulation of statistical analysis with the intention of drawing unwarranted conclusions - are trivial.

CHAPTER FOUR

RESULT

Respondents' profile

The demographic characteristics of the respondents (Table 1) show that the modal age group was 40-49 years for UNIBEN/UBTH [33 (42.3%)], AAU/ISTH [24 (66.7%)] and for all respondents combined [61 (46.2%)]. The modal age group for DELSU/SH was 30-39 years. For each centre and for all centres combined, males, married, protestants/pentecostals were modal for sex, marital status and religion respectively.

The respondents came from a wide range of academic disciplinary backgrounds and ranks (Table 2). Researchers in Surgery, 28 (21.2%) and in the rank of Lecturer I, 50 (37.6%) were the modal groups.

Majority, 100 (75.2%), of the respondents had had at least one previous training in research ethics (Table 3). The modal type of training was workshop or seminar (72.0% of those who had been trained). A total of 47 (47.0%) of those who have been trained hold a certificate or diploma.

Researchers' Awareness of the Requirements for Research to be Ethical according to the National Code of Health Research Ethics

Most of the respondents were aware of each of the criteria for research to be ethical as specified in Nigeria's National Code of Health Research Ethics. Informed consent and respect for participants were the best known criteria, having been corrected mentioned by 126 (96.2%) respondents. The least known requirement was the need for independent review by persons unaffiliated with the research, 99 (75.6%).

Knowledge of research ethics as different from clinical ethics

The respondents were required to respond to the statement "Health research means clinical ethics in research settings" with a "Yes" or "No" answer. A "No" response constituted a correct answer. Majority of the respondents, 97 (78.2%), gave a wrong response (Fig 1).

A greater proportion of clinicians, 93/?? (79.5%) (holders of the MBBS or BDS degree) compared to non-clinicians 4/?? (57.1%) gave a wrong answer to this question.

Practice of research misconduct

The most frequently committed type of research misconduct was fabrication which was reported by 19/?? (15.7%), (Table 5). Other commonly recorded types of research misconducts include inadequate record keeping, 39 (30.5%), followed by the use of inappropriate or inadequate research design, 18 (14.2%) and unauthorised use of confidential information, 15 (12.1%).

Of 125 participants who responded to at least one statement on the major misconducts, 29 (23.2%) had committed at least one of the three major misconducts. Of the total of 132 participants who had responded to at least statement on the misconducts, 72 (54.6%) had committed at least one of all the itemised misconducts.

Barriers to Ethical Conduct of Health Research

The most frequently indicated barriers to the ethical conduct of health research were the lack of funds, 95 (74.8%), lack of facilities, 93 (72.7%), inadequate training in research ethics, 57 (45.6%) and inadequate training in research methods, 58 (45.3%). The ordered distributions (strength of agreement) also followed a similar pattern (Table 6).

Motivators of Ethical Conduct of Health Research

Table 7 shows that the provision of training for research methods and research ethics, 122 (95.31%) and funding for research, 119 (93.0%) were the major motivators of the ethical conduct of health research in this population, and in that order of strength of agreement and frequency. Among the other motivators (open-ended), the provision of facilities and physical space was the most frequent motivator stated.

Training in Research Ethics and Knowledge of all Itemised Requirements for Ethical Research

Of the 100 respondents who had been trained on research ethics, 39 (39.0%) knew all the itemised requirements for ethical research compared to 11 (33.3%) out of XXX who had not been trained (Table 8). This difference was not statistically significant ($p=0.56$).

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Committal of at Least One Research Misconduct

In Table 9, among the individual criteria for ethical research, a statistically significant explanatory or predictor variable was the lack of knowledge that independent review by persons unaffiliated with the study was an ethical requirement for research. Increasing number of respondents who had the knowledge of this criterion was directly related to decreasing number of those who would commit at least one research misconduct ($p=0.01$; $OR=0.25$; 95% CI) .

Table 10 shows that a statistically significant explanatory variable was the lack of knowledge of all itemised requirements for research to be ethical. Increasing number of respondents who had this knowledge was directly related to decreasing number of those who would commit at least one research misconduct ($p=0.02$; $OR=0.42$ CI95%) while holding the other variable constant. "Training in research ethics" (the lack of it) is not a statistically significant explanatory variable ($p=0.087$; 95% CI of OR included 1.00), although the $OR< 0.5$ and therefore noteworthy.

In Table 11, no barrier to the ethical conduct of research was a statistically significant explanatory variable of in this model was statistically significant (all $p>0.05$; OR of all 95% CI included the null value of 1.00) as an explanatory variable of the committal of one at least one research misconduct. In addition, none of the OR was >2.00 or <0.50. Thus, change in the number of respondents who expressed these barriers to ethical research was not related to a corresponding no significant change in the number that would commit at least one research misconduct.

Table 12 shows that the lack of training in research ethics is inversely associated with committal of at least one instance of research misconduct ($p=0.04$; $OR=0.38$; 95% CI of OR excluded 1.00) .

Committal of at Least One "Major" Research Misconduct (Fabrication, Falsification and Plagiarism)

Table 13 shows that lack of knowledge that independent review by persons unaffiliated with a study was an ethical requirement for research is inversely associated with committal of at least one episode of research misconduct. Increasing the number of respondents who had the knowledge of this criterion was directly related to a decreasing number of those who would commit at least one major research misconduct (fabrication, falsification or plagiarism) ($p=0.01$; OR=0.22; 95% CI of OR excluded 1.00) while holding other variables constant. Explanatory variables with OR ≥2.0 (knowledge of the criterion of "social and scientific value") and ≤0.5 (knowledge of the criteria of "valid attempts to minimize risks and maximize health benefits," "informed consent," "trust at the heart of researcher-participant relationships**"** and "protecting the interest of participants and other stakeholders") were also noteworthy, though their 95% CI and p values did not meet the criteria for statistical significance.

The demographic and academic characteristics of the respondents and the variables representing barriers and motivators to the ethical conduct of research did not demonstrate statistical significance as predictors of the committal of at least one "major" research misconduct.

Unauthorised Use of confidential information

A statistically significant explanatory or predictor variable for the unauthorised use of confidential information was the discouragement experienced by respondents from senior colleagues who showed unwholesome example (Table 14). Rising number of respondents who were thus discouraged was directly related to a reducing number of unauthorised users of confidential information ($p=0.014$; OR=0.36; 95% CI for OR excluded the null value of 1.00) while holding other variables constant.

Knowledge that informed consent is required for ethically conducted research

In Table 15, none of the explanatory variables was statistically significant (all $p>0.05$; OR of all 95% CI included the null value of 1.00; no OR was >2.00 or <0.50). Thus, change in the number of respondents trained in research ethics, years of conducting research or rank was not related to a corresponding significant change in the number that would know that informed consent was required for ethical conduct of research.

Inadequate Knowledge or Training in Research Ethics

In Table 16, two statistically significant explanatory variables of inadequate knowledge or training in research ethics were committal of at least one research misconduct ($p=0.015$; OR=2.74; 95% CI of OR excluded 1.00) and indicating training in research ethics and research methods as motivators for ethical conduct of research ($p=0.001$; OR=0.24; 95% CI of OR excluded 1.00). Rising number of respondents who committed at least one ethical misconduct was directly related to a rising number of those who identified inadequate knowledge or training in research ethics as a barrier to conducting research ethically, while holding other variables constant. On the other hand, a rising number of respondents who indicated training in research ethics and research methods as motivators for ethical conduct of research was associated with a reducing number of those who identified inadequate knowledge or training in research ethics as a barrier to conducting research ethically, while holding other variables constant.

Inadequate Knowledge or Training in Research Methods

In Table 17, two statistically significant explanatory or predictor variables in this model were committal of at least one research misconduct (p=0.043; 95% CI of OR excluded 1.00) and indicating training in research ethics and research methods as motivators for ethical conduct of research (p=0.003; 95% CI of OR excluded 1.00). Rising number of respondents who committed at least one ethical misconduct was directly related to a rising number of those who identified inadequate knowledge or training in research methods as a barrier to conducting research ethically, while holding other variables constant. On the other hand, a rising number of respondents who indicated training in research ethics and research methods as motivators for ethical conduct of research was associated with a reducing number of those who identified inadequate knowledge or training in research methods as a barrier to conducting research ethically, while holding other variables constant.

Overlooking Others' Use of Incorrect Data When in a Position to Act against It

In Table 18, two explanatory or predictor variables were statistically significant – inadequate knowledge or training in research ethics (p=0.029; OR=0.31; 95% CI of OR excluded 1.00) and lack of access to sufficient funds for research (p=0.029; OR=0.26; 95% CI of OR excluded 1.00). Rising number of respondents who identified these variables as barriers to conducting research ethically are associated with reducing numbers of those would overlook others' use of incorrect data when in a position to act against it, other variables being constant.

Using Inappropriate or Inadequate Research Design

In Table 19, two statistically significant explanatory or predictor variables were inadequate knowledge or training in research ethics (p=0.02; OR=0.32; 95% CI of OR excluded 1.00) and colleagues' mockery at efforts to conduct research ethically ($p=0.024$; OR=0.26; 95% CI of OR excluded 1.00). Rising number of respondents who identified these variables as barriers to conducting research ethically was associated with a reducing number of those who would use inappropriate or inadequate research design, other variables being constant. A third explanatory or predictor variable was inadequate facilities for good quality research, but its statistical significance was borderline ($p=0.049$; OR=0.2.12; lower tail of confidence limit of OR = 1.00), other variables being constant.

Inadequate Rerecord Keeping

In Table 20, the only statistically significant explanatory or predictor variable was inadequate knowledge or training in research ethics ($p=0.029$; OR=0.37; 95% CI of OR excluded 1.00). Rising number of respondents who identified these variables as barriers to conducting research ethically was associated with a reducing number of those who would overlook others' use of incorrect data when in a position to act against it, other variables being constant.

CHAPTER FIVE

DISCUSSION

Empirical evidence provides much of the explanation of the patterns of variation in the demographic and academic profiles of the respondents. The predominance of respondents in the middle age group reflects the relative age maturity of lecturers in the medical schools compared to the general university, a fact that is related to the near absence Lecturer II or a lower rank in medical schools. The gender tilt in favour of males is consistent with the pattern in the medical school and may reflect the restrictive gender pattern in the pursuit of medical postgraduate qualifications (for example, females rarely specialise in General Surgery, Orthopaedics, Traumatology and Morbid Anatomy). Even the literature on medical research and ethics tend to show the preponderance of males. The significance of these variations and their possible implications for research ethics are areas that require more detailed studies in future.

The majority of the respondents (75.2%) had had one or more forms of training in research ethics, mostly from workshops and seminars as stand-alones or built in as parts of postgraduate training programmes. In a study in the United Kingdom, only 17.0% of newly appointed medical consultants reported having received any training in research ethics.[14] On one hand, the difference in the percentages could partly be explained by the difference in the characteristics of the study participants: newly appointed consultants outside Nigeria may not have had as long a period in research involvement to seek or be offered training in research ethics. On the other hand, it is noteworthy that since consultants in Nigeria have had postgraduate training involving thesis writing, they are expected to have been trained in research methods, including research ethics. But a few consultants in this study also claimed that they had not had training in research ethics. One may thus infer that, from place to place, there are disparities and gaps in the curricular content of training in research methods with respect to the inclusion of research ethics. Recent positive efforts in Nigeria in this regard are remarkable. The diploma training programme in research ethics is relatively recent in the country, the only one known being the one administered by the West African Bioethics Training Programme based in Ibadan. The same institution administers a Masters Degree programme (sponsored as shown on the cover of this work) awarded by the University of Ibadan. With this arrangement, it is expected that the number, proportion and level of training of health researchers in research ethics will rise with expected value addition to the health and research enterprises in the country.

The majority of the respondents could not identify that research ethics is not clinical ethics in research settings, this being worse with holders of the MBBS or BDS degrees, with or without additional qualifications, than with others. This variation is not surprising since medical doctors and dental surgeons often carry out their patient-care duties based on consent given for clinical care and may equate the concept with that of research ethics. Yet, the distinction is important from many points of view including, as shown in this study and discussed below, the non-assumption that consent given by patients for clinical care obviates consent for research.

The respondents had generally good knowledge of criteria for research to be ethical. The high percentages of correct responses may have partly stemmed from the fact that the eliciting question was closed-ended. Respect for potential and enrolled research participants and informed consent were the best known requirements for health research to be ethical. Respect for potential and enrolled participants may have been so well known because it is consistent with clinical ethical conduct. It is not surprising that informed consent was also known by almost all respondents as a criterion for health research to be ethical especially since it was already a well known concept in clinical ethics too. This is an encouraging finding since, as Nigeria's National Code of Health Research Ethics puts it, informed consent is a *sine qua non* for ethical conduct of research.[3] However, it must be noted that while 96.2% of respondents had this knowledge (that is, 3.8% lacked the knowledge), as many as 12.1% indicated that they had committed misconduct involving unauthorised use of confidential information on individuals. This is obviously antithetical to informed consent since informed consent was not obtained on the occasions of their unauthorised use of confidential information on individuals. The higher percentage of those did the wrong practice than those who lacked the required knowledge illustrates a knowledge-practice gap. Similarly, 90.7% of respondents indicated knowledge of scientific validity as a prerequisite for ethical research (that is, 9.3% lacked this knowledge), whereas as many as 14.2% indicated that they had committed misconduct involving the use of inappropriate or inadequate research design. In this and preceding instances, the percentages suggest that knowledge was better than practice. This gap demonstrates the fact that, though the actual sequence and time interval between knowledge and practice were unknown, knowledge is not a guarantee for practice. Unfortunately, no other study was found to have identified gaps between the knowledge and practice of research ethics.

It is interesting that independent review of research by persons unaffiliated with it and protection of the interest of participants, researchers, sponsors and communities were the least known ethical requirements. The practice of independent review of proposals and scientific papers, unknown by almost one-quarter of the respondents of this study, is probably well-known in the scientific world. What may be less well-known, as may be the case in this study, is the fact that it is an ethical requirement. This explanation may also apply to the requirement that the interest of participants, researchers, sponsors and communities be protected. These findings point to the importance of emphasising these practices as ethical requirements.

It is remarkable that the knowledge that independent review of research is an ethical requirement is associated with a reduced likelihood of committing any of the itemised acts of research misconduct and, in particular, FFP (fabrication, falsification and plagiarism). This association is akin to the precautionary principle since independent review of research by persons unaffiliated with it enables the detection and prevention of potential and actual harm to research participants and, possibly, the general public as might be caused through a research misconduct. This suggests that continuing education is required to update knowledge and avert misconduct.

The most frequently practiced research misconduct overall was inadequate record keeping. This may not be unexpected since it may be commonplace among researchers that certain information that was not provided for in data collection plans are later found, during analysis, to be required. Beyond core study design issues, inadequate record keeping may also be associated with limited resources, such as competent research assistants and time available or allocated to research, and being able to determine the type of record that should be kept. This misconduct can also be in the forms of discarding data too soon after a study or incomplete data transfer for the purpose of storage for future use. This study elicited self-acknowledged poor knowledge of or training in research ethics as the most important predictor of inadequate record keeping, thus suggesting that this training is required to reverse the challenge of inadequate. More studies are required in future to provide details on the nature of this misconduct.

The second most commonly committed research misconduct was fabrication, which refers to the intentional making up of data or results and recording or reporting them. Falsification is the second most frequent misconduct among the FFP. Data on fabrication has been reported in the literature either alone or, more often, with falsification or in both ways, perhaps the misconducts are very closely related. For example, of the 22 cases on which investigation was completed in 2005, the United States Office of Research Integrity identified 2 cases of fabrication alone, 3 of falsification alone, two of fabrication with falsification and one of plagiarism.[19] The ethical concerns about fabrications in health research has continued to heighten especially following cases like the South Korean researcher Woo Suk Hwang who faked research on cloned human stem-cell lines.[20, 21] It is noteworthy that some statisticians have responded to the concerns about data fabrication in clinical trials by developing statistical methods for the detecting them.[22] The methods may not be perfect, but may be very useful.

The third most commonly committed research misconduct was inappropriate or inadequate research design. A statistically significant association was found between this misconduct and the assertion that research facilities were deficient. This could be explained on the grounds that the availability of good facilities could have been an impetus for appropriate research designs. This is an important challenge to address if good quality research is expected from health research institutions in Nigeria. A statistically significant inverse relationship was found between inappropriate or inadequate research design and researchers' colleagues' mockery at their efforts to conduct research ethically. One way to understand this finding is that the mockery is a motivation, rather than a barrier, to using appropriate and adequate research designs. Otherwise, it could be an artefactual finding. Expectedly, inappropriate or inadequate research design was associated (though not statistically significant, despite an odds ratio of 2.11) with self-acknowledged poor training and knowledge of research methods, a point that further underscores the need for improved training. It is strange to note that there was a statistically significant inverse relationship between this misconduct and self-acknowledged poor training and knowledge of research ethics. This was unexpected because a direct linear relationship would have been logical. However, it may be that the feeling of inadequacy in knowledge or training in research ethics is a motivation for using appropriate and adequate research designs. Otherwise, it could be an artefactual finding.

This study showed that about 54.6% of respondents indicated that they had committed at least one research misconduct (among the types presented in the study). This value is roughly within the range of those in other studies: 5.7% of newly appointed consultants in a United Kingdom study,[14] 15.1% in a United States study,[16] 33% (for the ten most serious misconducts in only the preceding 3 years) in another United States survey,[17] 10-50% of all publications (regarding questionable research practices),[24] a pooled value of up to 33.7% in a world-wide-web-based meta-analysis[25] and about 77% of alleged cases within the preceding 10 years as reported by an editor.[26] Marked limitations exist in attempts to compare these data on research misconduct largely because of wide variations in the specific variables measured in different studies, the characteristics of respondents (e.g. their specific fields of research), the method of collecting the data (e.g. how confidentiality was built into data collection procedures to permit true responses), the sensitivity and associated integrity of the responses and the duration under consideration for the misconduct. The lesson remains, however, that research misconduct is a widespread practice among health researchers in different parts of the world.

About 23.2% of the respondents had committed at least one of FFP; no study was found to have made the same measurement. However, the earlier mentioned US-based survey by Martinson et al[17] showed that 0.3% of the respondents had committed either fabrication or falsification in the preceding 3 years among early- and mid-career scientists. Keeping in mind the population and durational differences between the studies, this study and the Martinson et al study share the following comparable data respectively: inadequate record keeping (30.5%/27.5%); using inappropriate or inadequate research design (14.2%/13.5%); unauthorised use of confidential information (12.1%/1.7%); overlooking others' use of incorrect data when in a position to act against it (9.8%/12.5%); publishing the same data or results in two or more publications (5.6%/4.7%); failing to present data that contradict one's own research (4.0%/6.0%); having relationships with research students or research participants that may be interpreted as questionable (1.6%/1.4%); and manipulating the methodology or results of a study in response to pressure from a funding source (0.8%/15.5%). For most of the variables, the values are comparable. But the much higher rate of unauthorised use of confidential information in this study is probably related to the fact that almost all the respondents were clinicians whose patients' data were within easy reach; Martinson's study participants were health scientists,[17] most of whom may not have had ready access to patients' data.

In examining the barriers and motivators to ethical conduct of research, training in research methods and ethics and the provision of funds and facilities were the key issues identified – the absence of these being barriers and their presence being motivators required in building capacity to further incentivise researchers towards research and its ethical conduct. Training in research ethics is being addressed to a reasonable extent as discussed above with ripple effect expected with time. However, this study showed that, judging by statistical significance, those who were trained in research ethics did not know ethical requirements for research better than those who were not. But the knowledge of these requirements was then shown to be explanatory to the non-committal of an ethical misconduct if training status were held constant. These relationships call to question the content of the training that the researchers in this survey had had, and indicate that satisfactory training is still required to ensure knowledge of ethical requirements.

Interestingly, the respondents who did not identify the lack of training in research ethics and research methods as barriers to their ethical conduct of research were more likely than others to identify training in these areas as motivators. Perhaps these respondents were those whose knowledge provided a basis for desiring more value from more knowledge.

Again, those who indicated inadequate knowledge or training in research ethics and research methods and who had not been trained in research ethics were, in their separate categories, more likely to have committed at least one of the itemised research misconducts, a point which again highlights the need for more training in both research ethics and research methods. A favourable observation in this direction was the strong association between these self-acknowledged inadequacies and the indication that training in these areas would motivate the respondents to conduct research ethically.

Self-identified knowledge gap in research ethics (rather than research methods) was specifically shown to be an explanatory variable in the respondents' use of inappropriate or inadequate research designs, inadequate record keeping and overlooking others' use of incorrect data when in a position to act against it. This underscores the need to thoroughly integrate both research ethics and research methods in training curricula for both subjects.

It is important to note that, in this study, factors like age, number of years of conducting research and academic rank were not significant explanatory variables with respect to knowledge of ethics and the identification of knowledge gaps as barriers. Indeed, this study showed that unwholesome examples of unethical research by senior colleagues were significant determinants for the unauthorised use of confidential data. This underscores the need for re-orientation and training for all, irrespective of the aforementioned characteristics.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

CONCLUSION

The study demonstrated that informed consent and respect for participants were the best known requirements for research to be ethical, each having a correct response of 96.2%. The least known requirement was independent review by persons unaffiliated with the research (75.6%). Of the 100 respondents who had been trained on research ethics, 39 (39.0%) knew all the itemised requirements for ethical research compared to 11 (33.3%) who had not been trained. This difference was not statistically significant ($p=0.560>0.05$).

Among the major research misconducts, the most frequently committed was fabrication, 19 (15.7%), and this was the second most commonly committed of all types of the itemised misconducts. Among the other research misconducts, inadequate record keeping was the commonest, 39 (30.5%), followed by the use of inappropriate or inadequate research design, 18 (14.2%) and unauthorised use of confidential information, 15 (12.1%).

The most frequently indicated barriers were the lack of funds, 95 (74.8%), lack of facilities, 93 (72.7%), inadequate training in research ethics, 57 (45.6%) and inadequate training in research methods, 58 (45.3%).

Provision of training for research methods and research ethics, 122 (95.31%) and funding for research, 119 (93.0%) were the major motivators, and in that order of strength of agreement. Among the other motivators, the provision of facilities and physical space was the major motivator stated.

The knowledge of ethical requirements for research was shown to be explanatory to the non-committal of an ethical misconduct. Again, those who indicated inadequate knowledge of research ethics and research methods and who had not been trained in research ethics were, in their separate categories, more likely to have committed at least one of the itemised research misconducts. Self-identified knowledge gap in research ethics (rather than research methods) was specifically shown to be an explanatory variable in the respondents' use of inappropriate or inadequate research designs, inadequate record keeping and overlooking others' use of incorrect data when in a position to act against it.

These findings point to the need for a comprehensive support programme for training in research ethics and research methods and to promote best practices in the conduct of health research.

RECOMMENDATIONS

Given the findings of this study, the major recommendations are as follows.

1. There is an urgent need to continuously train all researchers in research methods and research ethics in an integrated manner that assures best practices. This should be taken as a priority by Nigerian universities, teaching hospitals and research institutes. In this regard, the support of local and foreign experts from countries where a strong research and research ethics culture has been built. Such support could include scholarships and curricular development.

2. All stakeholders including all tiers of government, the private sector and the international community should promote research by setting national priorities, projects and agendas. This can be done through the Federal Ministry of Science and Technology and the Federal Ministry of Health. The National Policy on Health has a section that stipulates that priorities in health research are to be set from time to time and the need for broad-based partnership.

3. In the light of the above, there is the need to budget for and actually fund research. Again, all stakeholders are required in this regard. That way, researchers will be motivated to devote time to the conduct of research.

4. There is the need to engage in international collaborative research where experience can be gained by local researchers in best practices in research and research ethics.

5. In order to build a satisfactory research culture, there is the need to have good research infrastructure and facilities. Again, this should be taken as a priority by all stakeholders. It would require a sustainable science and technology base that can guarantee maintenance culture and continuity.

APPENDICES

TABLES AND FIGURES

Table 1.
Demographic Characteristics of Respondents by Centre

DEMOGRAPHIC CHARACTERISTICS	CENTRES			
	UNIBEN/UBTH (%) [n=78]	**AAU/ISTH (%) [n=36]**	**DELSU (%) [n=19]**	**TOTAL (%) [N=133]**
AGE IN YEARS*				
30-39	19 (24.4)	7 (19.4)	9 (50.0)	35 (26.5)
40-49	33 (42.3)	24 (66.7)	4 (22.2)	61 (46.2)
≥50	26 (33.3)	5 (13.9)	5 (27.8)	36 (27.3)
SEX				
Male	59 (75.6)	33 (91.7)	16 (84.2)	108 (81.2)

Female	19 (24.4)	3 (8.3)	3 (15.8)	25 (18.8)
MARITAL STATUS*				
Single	1 (1.3)	2 (5.6)	2 (11.1)	5 (3.8)
Married	76 (97.4)	34 (94.4)	16 (88.9)	126 (95.5)
Widow(er)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.8)
RELIGION**				
Protestants/ Pentecostals	52 (66.7)	18 (50.0)	9 (47.4)	79 (59.4)
Catholic	24 (30.8)	16 (44.4)	7 (36.8)	47 (35.3)
Islam	0 (0.0)	2 (5.6)	0 (0.0)	2 (1.5)
Others	2 (2.6)	0 (0.0)	3 (15.8)	5 (3.8)
ETHNIC GROUP				
Esan	13 (16.7)	16 (44.4)	2 (10.5)	31 (23.3)
Ibo	18 (23.1)	4 (11.1)	6 (31.6)	28 (21.1)
Bini	23 (29.5)	3 (8.3)	1 (5.3)	27 (20.3)
Urhobo	6 (7.7)	3 (8.3)	6 (31.6)	15 (11.3)
Yoruba	7 (9.0)	4 (11.1)	1 (5.3)	12 (9.0)
Others	11 (14.1)	6 (16.6)	3 (15.8)	20 (15.0)

*One missing value
**Jehovah's Witness and African Traditional Religion were each 0 frequency. No respondent specified "others".

Table 2.
Departments and Ranks of Respondents by Centre

ACADEMIC CHARACTERISTICS	CENTRES (%)			
	UNIBEN/UBTH [n=78]	AAU/ISTH [n=36]	DELSU [n=19]	TOTAL [N=133]
DEPARTMENT*				
Surgery	19 (24.7)	8 (22.2)	1 (5.3)	28 (21.2)
Paediatrics	12 (15.6)	5 (13.9)	0 (0.0)	17 (12.9)
Obstetrics and Gynaecology	6 (7.8)	5 (13.9)	4 (21.1)	15 (11.4)
Medicine	6 (7.8)	5 (13.9)	0 (0.0)	11 (8.3)
Radiology	5 (6.5)	5 (13.9)	0 (0.0)	10 (7.6)

Community Health	4 (5.2)	4 (11.1)	1 (5.3)	9 (6.8)
Dentistry	7 (9.1)	2 (5.6)	0 (0.0)	9 (6.8)
Mental Health	5 (6.5)	1 (2.8)	0 (0.0)	6 (4.5)
Haematology	4 (5.2)	0 (2.8)	2 (10.5)	6 (4.5)
Nursing	0 (0.0)	0 (0.0)	5 (26.3)	5 (3.8)
Pharmacology	2 (2.6)	0 (0.0)	3 (15.8)	5 (3.8)
Microbiology	1 (1.3)	0 (0.0)	2 (10.5)	3 (2.3)
Morbid Anatomy	2 (2.6)	1 (2.8)	0 (0.0)	3 (2.3)
Family Medicine	3 (3.9)	0 (0.0)	0 (0.0)	3 (2.3)
Chemical Pathology	1 (1.3)	0 (0.0)	1 (5.3)	2 (1.5)
RANK				
Professor	5 (6.4)	0 (0.0)	2 (10.5)	7 (5.3)
Associate Professor/ Reader	5 (6.4)	2 (5.6)	1 (5.3)	8 (6.0)
Senior Lecturer	29 (37.2)	11 (30.6)	5 (26.3)	45 (33.8)
Lecturer I	27 (34.6)	20 (55.6)	3 (15.8)	50 (37.6)
Hospital Consultants	12 (15.4)	2 (5.6)	0 (0.0)	14 (10.5)
Lecturer II	0 (0.0)	1 (2.8)	8 (42.1)	9 (6.8)

*One missing value

Table 3.
Respondents who had been trained in Research Ethics

N = 100	**Type of training**	**Frequency***	**% of n**
	A workshop or seminar	72	72.0
	A course or part of a course in a diploma or degree	41	41.0
	A certificate or diploma	47	47.0
	A degree	2	2.0
	None	33	-

- **Multiple responses allowed**

Table 4.
Awareness of the Requirements for Ethical Research

Requirements*	Frequency: Responses	Frequency: Correct Answers	Percentage Providing Correct Answers
Respect for potential and enrolled participants	132	127	96.2
Informed consent	131	126	96.2
Trust at the heart of researcher-participant relationships	130	123	94.6
Valid attempts to minimize risks and maximize health benefits	132	122	92.4
Conduct in accordance with international standards	132	120	90.9
Social or scientific value	129	117	90.7
Scientific validity, such as unbiased measurements and analysis	129	117	90.7
Fair selection of participants	131	114	87.0
Protection of the interest of participants, researchers, sponsors and communities	131	107	81.7
Independent review by persons unaffiliated with the research	131	99	75.6

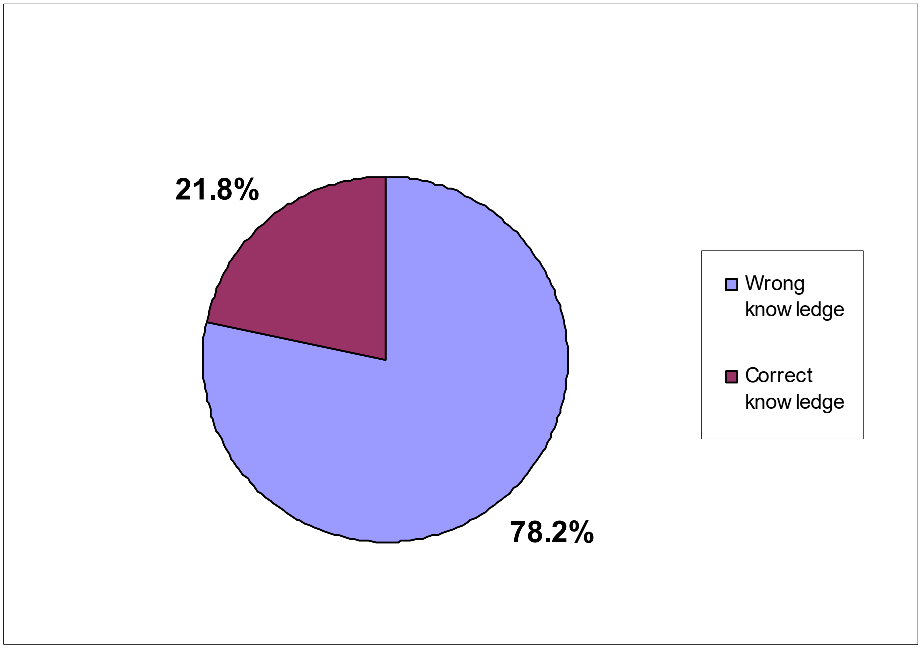

Figure 1. Knowledge of research ethics as different from clinical ethics

Table 5.
Practice of Research Misconduct

Research Misconducts	Frequency		% of Responses Involved in Unethical Conduct
	Responses	Involved in Unethical Conduct	
Major Research Misconducts			
Making up data or results and recording or reporting them (fabrication)	121	19	15.7
Manipulating research materials, equipment, processes, or changing or omitting data or results (falsification)	122	13	10.7
Appropriation of another person's ideas, processes, results, or words, partly or wholly without giving appropriate credit (plagiarism)	122	6	4.9
Other Research Misconducts			
Inadequate record keeping	128	39	30.5
Using inappropriate or inadequate research design	127	18	14.2
Unauthorised use of confidential information (such as the use of data on patients that consented to clinical care but not to research)	124	15	12.1
Overlooking others' use of incorrect data when you were in a position to act against it	123	12	9.8
*Publishing the same data or results in two or more publications	124	7	5.6
*Manipulation of statistical analysis with the intention of drawing conclusions beyond what the data warrant	119	6	4.8
*Failing to present data that contradict one's own research	124	5	4.0
Having relationships with research students or research participants that may be interpreted as questionable	128	2	1.6
Manipulating the methodology or results of a study in response to pressure from a funding source	128	1	0.8

Table 6.
Barriers to Ethical Conduct of Health Research

Barriers experienced	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree	Total
Research participants do not have enough education to bother about informed consent	4	28	9	54	36	131
Research participants do not have enough time to bother about informed consent	3	23	9	60	60	129
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	33	60	8	23	4	128
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	8	9	5	71	35	128
My knowledge or training in research methods is not good enough	13	45	10	46	14	128
I do not have access to sufficient funds for my research	45	50	8	20	4	127
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	11	14	7	61	34	127
My knowledge or training in research ethics is not good enough	10	47	9	47	12	125
My senior colleagues discourage me by their unwholesome example of unethical research	5	8	11	70	31	125
My colleagues mock me because I make efforts to conduct research ethically	0	5	9	65	46	125

Table 7.
Motivators of Ethical Conduct of Health Research

Motivators	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree	Total
Providing training in research methods and research ethics	84	38	4	0	2	128
Improving the funding of research	83	36	3	5	1	128

Other specified motivators (unordered)	
Improving research facilities including physical space	9
Improving the quality of research and disseminating and applying research findings	3
Reducing official responsibilities to make enough time available for research	2
Sponsorship for scientific conferences abroad	1

Table 8.
Training in Research Ethics and Knowledge of all Itemised Requirements for Ethical Research

a. Contingency table and chi-squared analysis

		Previous training in research ethics		Total N (%)
		Yes N (%)	**No N (%)**	
Knowledge of all itemised requirements for ethical research	**Yes**	39 (39.0)	11 (33.3)	50 (37.6)
	No	61 (61.0)	22 (66.7)	83 (62.4)
Total		**100 (100.0)**	**33 (100.0)**	**133 (100.0)**

χ^2=0.34; p=0.56

b. Bivariate logistic regression

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	**Upper**
Training in research ethics	0.25	0.561	1.28	0.56	2.93
Constant	-0.69	0.061	-	-	-

Table 9.
Multiple Logistic Regression of Committal of at Least One Research Misconduct [Explanatory Variables: Knowledge of Individual Criteria for Ethical Research]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
Social or scientific value	0.70	0.350	2.01	0.46	8.73
Scientific validity	0.32	0.665	1.37	0.32	5.78
Fair selection of participants	0.49	0.494	1.63	0.40	6.61
Valid attempts to minimize risks and maximize health benefits	-0.75	0.465	0.47	0.06	3.52
Independent review by persons unaffiliated with the research	-1.39	0.011	0.25	0.09	0.73
Informed consent	-1.04	0.498	0.35	0.02	7.21
Respect for potential and enrolled participants	0.15	0.900	1.16	0.11	12.0
Trust at the heart of researcher-participant relationships	-0.26	0.813	0.77	0.09	6.71
Protecting the interest of participants and other stakeholders	-0.58	0.286	0.56	0.19	1.63
Following international standards	0.60	0.458	1.82	0.37	8.84
Constant	1.58	0.406	-	-	-

Table 10.
Multiple Logistic Regression of Committal of at Least One Research Misconduct [Explanatory Variables: Knowledge of and Training in Research Ethics]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
Knowledge of all itemised requirements for ethical research	-0.86	0.020	0.42	0.20	0.88
Training in research ethics	-0.75	0.087	0.47	0.20	1.12
Constant	1.09	0.009	-	-	-

Table 11.
Multiple Logistic Regression of Committal of at Least One Research Misconduct [Explanatory Variables: Barriers to Ethical Conduct of Research]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
My knowledge or training in research methods is not good enough	0.05	0.871	1.05	0.59	1.87
My knowledge or training in research ethics is not good enough	-0.27	0.373	0.76	0.42	1.39
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	-0.05	0.810	0.95	0.61	1.48
I do not have access to sufficient funds for my research	0.04	0.860	1.04	0.68	1.60
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	-0.09	0.717	0.91	0.57	1.48
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	-0.04	0.882	0.96	0.54	1.68
My senior colleagues discourage me by their unwholesome example of unethical research	-0.06	0.849	0.94	0.50	1.77
My colleagues mock me because I make efforts to conduct research ethically	-0.57	0.174	0.56	0.25	1.29
Research participants (subjects) do not have enough education to bother about informed consent	-0.28	0.418	0.75	0.38	1.49
Research participants (subjects) do not have enough time to bother about informed consent	0.30	0.434	1.36	0.63	2.91
Constant	3.99	0.006	-	-	-

Table 12.
Multiple Logistic Regression of Committal of at Least One Research Misconduct [Explanatory variables: Demographic and Academic Characteristics]

	Coefficient	p value	OR	95% CI of OR	
				Lower	Upper
Age	-0.00	0.920	1.00	0.93	1.07
Sex	0.62	0.201	1.85	0.72	4.75
Rank	-0.02	0.878	0.98	0.78	1.24
Multiple postgraduate qualifications	0.26	0.572	1.29	0.53	3.15
Number of research years	-0.03	0.369	0.97	0.90	1.04
Training in research ethics	-0.95	0.039	0.38	0.16	0.95
Constant	0.98	0.533	-	-	-

Table 13.
Multiple Logistic Regression of Committal of at Least One Major Research Misconduct
[Explanatory Variables: Knowledge of Individual Criteria for Ethical Research]

	Coefficient	p value	OR	95% CI of OR	
				Lower	Upper
Social or scientific value	1.07	0.347	2.91	0.31	27.08
Scientific validity	0.28	0.814	1.32	0.13	13.83
Fair selection of participants	-0.02	0.986	0.98	0.13	7.27
Valid attempts to minimize risks and maximize health benefits	-1.87	0.087	0.15	0.02	1.31
Independent review by persons unaffiliated with the research	-1.52	0.011	0.22	0.07	0.71
Informed consent	-1.38	0.395	0.25	0.01	6.02
Trust at the heart of researcher-participant relationships	-1.13	0.386	0.32	0.02	4.18
Protecting the interest of participants and other stakeholders	-0.95	0.155	0.39	0.11	1.43
Applying international standards	-0.32	0.706	0.72	0.13	3.88
Constant	3.54	0.136	-	-	-

"Respect for potential and enrolled participants" is a perfect predictor of committing at least one major research misconduct and is excluded from the model by default.

Table 14.
Multiple Logistic Regression of Unauthorised Use of confidential information
[Explanatory Variables: Barriers to Ethical Conduct of Research]

	Coefficient	p value	OR	95% CI of OR	
				Lower	Upper
My knowledge or training in research methods is not good enough	-0.51	0.306	0.60	0.23	1.59
My knowledge or training in research ethics is not good enough	0.36	0.485	1.44	0.52	3.97
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	0.19	0.606	1.21	0.59	2.48
I do not have access to sufficient funds for my research	0.12	0.715	1.13	0.58	2.20
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	-0.36	0.322	0.70	0.34	1.42
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	0.26	0.508	1.30	0.60	2.82
My senior colleagues discourage me by their unwholesome example of unethical research	-1.02	0.014	0.36	0.16	0.81
My colleagues mock me because I make efforts to conduct research ethically	0.48	0.381	1.62	0.55	4.78
Research participants (subjects) do not have enough education to bother about informed consent	-0.69	0.174	0.50	0.18	1.36
Research participants (subjects) do not have enough time to bother about informed consent	0.42	0.457	1.52	0.50	4.58
Constant	0.79	0.678	-	-	-

Table 15.
Multiple Logistic Regression of Knowledge that informed consent is required for ethically conducted research

	Coefficient	p value	OR	95% CI of OR	
				Lower	Upper
Rank	-0.13	0.620	0.88	0.54	1.45
Number of years conducting research	0.03	0.658	1.03	0.90	1.17
Training in research ethics	-0.35	0.760	0.70	0.75	6.65
Constant	3.63	0.031	-	-	-

Table 16.

Multiple Logistic Regression of Inadequate Knowledge or Training in Research Ethics

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
Training in research ethics	-0.11	0.807	0.89	0.36	2.20
Rank	0.16	0.205	1.17	0.92	1.49
Committal of at least one research misconduct	1.01	0.015	2.74	1.21	6.16
Indicates training in research ethics and research methods as motivators of ethical conduct of research	-1.44	0.001	0.24	0.10	0.54
Constant	0.77	0.364	-	-	-

Table 17.
Multiple Logistic Regression of Inadequate Knowledge or Training in Research Methods

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
Training in research ethics	0.16	0.724	1.17	0.49	2.80
Rank	0.20	0.098	1.22	0.96	1.54
Committal of at least one research misconduct	0.81	0.043	2.24	1.02	4.87
Indicates training in research ethics and research methods as motivators of ethical conduct of research	-1.10	0.003	0.33	0.16	0.69
Constant	0.05	0.951	-	-	-

Table 18.

Multiple Logistic Regression of Overlooking Others' Use of Incorrect Data When in a Position to Act Against it
[Explanatory Variables: Barriers to Ethical Conduct of Research]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
My knowledge or training in research methods is not good enough	0.69	0.149	2.00	0.78	5.13
My knowledge or training in research ethics is not good enough	-1.18	0.029	0.31	0.11	0.88
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	0.53	0.186	1.71	0.77	3.76
I do not have access to sufficient funds for my research	-1.37	0.039	0.25	0.07	0.93
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	-0.28	0.607	0.76	0.26	2.20
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	0.76	0.189	2.14	0.69	6.64
My senior colleagues discourage me by their unwholesome example of unethical research	-0.17	0.704	0.84	0.34	2.06
My colleagues mock me because I make efforts to conduct research ethically	-0.45	0.442	0.64	0.20	2.02
Research participants (subjects) do not have enough education to bother about informed consent	1.34	0.097	3.82	0.78	18.63
Research participants (subjects) do not have enough time to bother about informed consent	-1.21	0.167	0.30	0.05	1.66
Constant	-0.40	0.86	-	-	-

Table 19.

Multiple Logistic Regression of Using Inappropriate or Inadequate Research Design
[Explanatory Variables: Barriers to Ethical Conduct of Research]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
My knowledge or training in research methods is not good enough	0.75	0.093	2.11	0.88	5.06
My knowledge or training in research ethics is not good enough	-1.15	0.024	0.32	0.12	0.86
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	0.75	0.049	2.12	1.00	4.47
I do not have access to sufficient funds for my research	-0.40	0.311	0.67	0.31	1.45
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	-0.58	0.156	0.56	0.25	1.25
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	0.09	0.841	1.09	0.47	2.51
My senior colleagues discourage me by their unwholesome example of unethical research	0.17	0.762	1.18	0.40	3.48
My colleagues mock me because I make efforts to conduct research ethically	-1.44	0.044	0.24	0.06	0.96
Research participants (subjects) do not have enough education to bother about informed consent	-0.11	0.861	0.90	0.28	2.94
Research participants (subjects) do not have enough time to bother about informed consent	0.40	0.564	1.49	0.39	5.74
Constant	3.85	0.041	-	-	-

Table 20
Multiple Logistic Regression of Inadequate Rerecord Keeping
[Explanatory Variables: Barriers to Ethical Conduct of Research]

	Coefficient	*p* value	OR	95% CI of OR	
				Lower	Upper
My knowledge or training in research methods is not good enough	0.78	0.076	2.19	0.92	5.19
My knowledge or training in research ethics is not good enough	-0.99	0.029	0.37	0.15	0.90
The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent	-0.04	0.885	0.96	0.57	1.63
I do not have access to sufficient funds for my research	-0.17	0.541	0.84	0.49	1.46
I am urgent about publishing enough papers for my promotion; attention to ethics will delay me	0.34	0.334	1.41	0.70	2.82
I have too many other official responsibilities: I don't have that extra time for ethical considerations in research	0.02	0.967	1.02	0.47	2.20
My senior colleagues discourage me by their unwholesome example of unethical research	0.17	0.626	1.19	0.60	2.36
My colleagues mock me because I make efforts to conduct research ethically	-0.80	0.076	0.45	0.19	1.09
Research participants (subjects) do not have enough education to bother about informed consent	0.10	0.819	1.10	0.48	2.55
Research participants (subjects) do not have enough time to bother about informed consent	-0.40	0.413	0.67	0.26	1.75
Constant	2.60		-	-	-

QUESTIONNAIRE

I am Dr. Omokhoa ADELEYE. This questionnaire is a tool for a postgraduate thesis on ethical conduct among researchers on human participants. Kindly fill it truthfully. Your responses will be treated as **STRICTLY CONFIDENTIAL**. Filling this questionnaire is taken as consent, and it entitles you afterwards to a **FREE CD** containing national and international research ethics codes. Please ask me any question you may have about filling this questionnaire. You may reach me on any of the following numbers 08037212596, 08050567286. Thank you.

SECTION A

1. Age last birthday…….. **2.** Sex…… **3.** Ethnic group....……………………….

4. Rank (e.g., Snr. lecturer)……………… **5.** Qualifications (1st degree & above)……….…………

6. Religion/Sect, etc a. Roman Catholic b. Protestants/ Pentecostals c. Jehovah's Witness d. Islam e. African Traditional Religion f. Others (please specify)………………

7. Marital status. a. Single (never married) b. Married c. Divorced d. Separated e. Widow(er)

SECTION B

8. Number of years you have been conducting research......... (ii)Specialty................... (iii)Dept……………..

9. Have you ever had any training in research ethics? a. Yes b. No

10. If yes, what type of training? *(Tick Yes or No for each option)*

a.	A workshop or seminar	a. Yes	b. No
b.	A course or part of a course in a diploma or degree	a. Yes	b. No
c.	A certificate or diploma	a. Yes	b. No
d.	A degree	a. Yes	b. No

KEY

S AGR	**AGR**	**UND**	**D AGR**	**SD AGR**	**NA**
Strongly agree	**Agree**	**Undecided**	**Disagree**	**Strongly disagree**	**Not applicable**

Please tick the box that best represents your opinion or experience

	I. Health research ethics	AGR	UND	D AGR
1	Research ethics means clinical ethics in research settings			
2	Must have social or scientific value; improvement in well-being of participants or the population they represent or increase in scientific knowledge			
3	Must have scientific validity, such as unbiased measurements and analysis			
4	Must ensure fair selection of participants; the vulnerable should not be targeted for risky research and the socially advantaged should not be favoured for beneficial research			
5	Must be valid attempts to minimize risks and maximize health benefits			
6	For research to be ethical, it must undergo independent review by persons unaffiliated with the research			
7	Informed consent is essential to ethical research; information is given to the proposed participants who voluntarily decide whether or not to enrol and continue to participate			
8	There must be respect for potential and enrolled participants; they are allowed to withdraw at any time and their confidentiality is protected			
9	Nothing must be done to undermine the trust that is at the heart of researcher-participant relationships			
10	The interest of participants, researchers, sponsors and communities must be protected			
11	Must be conducted in accordance with international standards to further assure highest ethical and scientific standards			

	II. The following conditions are barriers to you in conducting research ethically	S AG R	AG R	UN D	D AG R	SD AG R	NA
1	My knowledge or training in research methods is not good enough						
2	My knowledge or training in research ethics is not good enough						
3	The facilities (equipment, logistics, etc) to carry out good quality research are deficient or absent						
4	I do not have access to sufficient funds for my research						
5	I am urgent about publishing enough papers for my promotion; attention to ethics will delay me						
6	I have too many other official responsibilities: I don’t have that extra time for ethical considerations in research						
7	My senior colleagues discourage me by their unwholesome example of unethical research						
8	My colleagues mock me because I make efforts to conduct research ethically						
9	Research participants (subjects) do not have enough education to bother about informed consent						
10	Research participants (subjects) do not have enough time to bother about informed consent						

	III. The following factors will motivate you to conduct research ethically	S AG R	AG R	UN D	D AG R	SD AG R	N A
1	Providing training in research methods and research ethics						
2	Improving the funding of research						
3	(Others, please specify)						
4	(Others, please specify)						
5	(Others, please specify)						

More…………..

	IV. Have the following ever been done?		**YES**	**NO**
1	Making up data or results and recording or reporting them	By you		
		By anyone you know		
2	Manipulating research materials, equipment, processes, or changing or omitting data or results	By you		
		By anyone you know		
3	Appropriation of another person's ideas, processes, results, or words, partly or wholly without giving appropriate credit	By you		
		By anyone you know		
4	Manipulation of statistical analysis with the intention of drawing conclusions beyond what the data warrant	By you		
		By anyone you know		
5	Having relationships with research students or research participants that may be interpreted as questionable	By you		
		By anyone you know		
6	Unauthorised use of confidential information (such as the use of data on patients that consented to clinical care but not to research)	By you		
		By anyone you know		
7	Failing to present data that contradict one's own research	By you		
		By anyone you know		
8	Overlooking others' use of incorrect data when you were in a position to act against it	By you		
		By anyone you know		
9	Manipulating the methodology or results of a study in response to pressure from a funding source	By you		
		By anyone you know		
10	Publishing the same data or results in two or more publications	By you		
		By anyone you know		
11	Using inappropriate or inadequate research design	By you		
		By anyone you know		
12	Inadequate record keeping	By you		
		By anyone you know		

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