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Ethical Principles & Responsible Conduct in Research

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ABSTRACT

Research has made important contribution to the progress and development of society. As a systematic and organized activity, the conduct of research must be guided by some ethical rules and guidelines in all the six phases of research including conception of the research, approval from a properly constituted ethics review committee, data collection, data analysis, report writing and dissemination. Research ethics is the application of rules or guidelines for the conduct of research. Ethics has important roles to play in all stages of research, from the conception of the research to the dissemination of the findings. The principles of research that regulate the conduct of research are respect for persons, beneficence, justice, and non-maleficence. Responsible researchers must apply these principles to ensure that research is conducted in ways that ensure that both the goals of science and ethics are achieved. Researchers have scientific and ethical obligation to conduct research with the highest degree of responsibility

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NATURE AND PHASES OF RESEARCH

Research plays a critical role in the development of human society. Research has contributed to the advancement in health, communication and technology which have in turn brought about improvement in living standards and quality of lives of human beings. Research is a systematic, deliberate process of investigation conducted to develop or contribute to generalizable knowledge (FHI, 2000). Research is a deliberate, intentional, planned effort to investigate and collect information on a given subject. Research is also aimed at providing solutions to problems affecting individuals, families, communities and the society at large. Research is therefore meant to fill an existing gap in knowledge on a specific subject.

There are six stages of research namely (1) development of a research plan, (2) submission of the plan to an Ethics Review Committee (ERC) for review and approval, (3) collection of information from field or laboratory, (4) processing, analyzing and interpreting the information, (5) writing a report of the process, and (6) the dissemination of findings through workshops, presentations at conferences and publications in peer-review journals..

ROLE OF ETHICS IN RESEARCH

Simply defined, ethics refers to the determination of what is right from what is wrong. When applied to research it refers

to acceptable code of conduct in all phases of the research process. It also refers to the rules and regulations that guide the conduct of research in ways that are generally considered acceptable by the global scientific community. Ethics has important roles to play in all stages of research. In response to history of abuses of research participants, several institutional, local, national and international guidelines are now available to regulate conduct of research. Some of the popular international guidelines are the Nuremberg Code, the Helsinki Declaration and the Council for International Organizations of Medical Sciences (CIOMS). In Nigeria, the Federal Ministry of Health developed in 2007 a national code to regulate conduct of health research in the country (FMOH, 2007).

PRINCIPLES OF RESEARCH ETHICS

All existing guidelines emphasize the role of four universal ethical principles that should be applied to all research involving human participants (Beauchamp and Childress, 2001). The principles are respect for persons, beneficence, non-maleficence and justice. The principle of respect for persons recognizes the fact that all persons have the rights to determine whether or not they will participate in a research. This principle is applied in practice through the process of informed consent. Informed consent takes place when a competent individual who is invited to participate in a research voluntarily agrees to do so after he/she has been provided with

adequate information about the research and he/she understands the information.

Beneficence requires investigators to minimize risk and maximize benefits of participation in research. The basis of this principle is an acknowledgement of the fact that all research have inherent risks and benefits and that it is the duty of the researcher to not only identify potential risks and benefits but also ensures that all persons who participate in the research enjoy full benefits and are exposed to minimal risks.

The principle of non-maleficence compels researchers not to cause any harm to study participants. It also requires that the researcher should at least not make the conditions of participants worse if he/she cannot make it better. Justice requires fairness in the process of recruitment of persons into any study. This principle acknowledges the fact that there are individuals who have diminished capacity to take actions to protect their own interests [CIOMS, 2002]. Such individuals are referred to as vulnerable. In Nigeria, examples of vulnerable persons include children, students, adolescents, patients with mental illness, prisoners, and the elderly persons. Researchers are therefore expected to take action to ensure that the rights of vulnerable persons are not violated when such persons participate in research.

The goal of these principles is to ensure that rights, safety and well-being of persons who participate in research are protected. However, experience has shown that the availability of these guidelines and awareness of the principles of research ethics has not eliminated incidence of abuse of research participants (Ajuwon and Kass, 2008).

OBLIGATIONS OF RESEARCHERS IN SIX PHASES OF RESEARCH

Researchers are expected to conduct research in a responsible manner to ensure that both the goals of science and ethics are achieved. With respect to goals of science, researchers must adopt the most appropriate design, procedures, methods and analysis that ensures that they collect valid and reliable information that are useful in meeting the needs of researchers and the society at large. The primary goal of ethics in research is the safety and well-being of persons who participate in research. The details of the obligations of researchers during each of the six phases of research for the attainment of these goals are discussed below.

Development of Research Plan: This is the stage when researchers develop the plan of how to conduct the research. This requires that researchers develop a proposal or protocol in which they will describe the entire process of how the research will be conducted. The obligations of a responsible researcher at this stage include a thorough review of existing literature on the subject of investigation to clearly define gaps in knowledge, an acknowledgement of sources of information, full description of the protocol, formulation of measurable objectives and clear delineation of variables of interest. Others are description of instrument for data collection and validation and reliability procedures, definition of study population, determination of adequate sample size/sampling procedures/systematic procedures for data collection, appropriate plan for data analysis and details of plan that will guarantee the safety of potential & actual study participants

before, during & after data collection. In addition, the responsible researcher must fully describe plan for ensuring safety of study participants. This includes development of an informed consent form and describes how this will be administered during data collection. An appropriate Informed Consent Form should be written in simple, easy-to-understand language and persons who will administer it should be adequately trained on how to use it. In addition, the researcher is expected to fully describe plans for confidentiality of data and privacy during data collection (CIOMS, 2002).

Approval of study protocol by Ethics Committee: One of the global best practice for ethical conduct of research is that researchers submit and obtain approval of the study protocol from an accredited ERC before the commencement of research. All existing guidelines (CIOMS, 2002) including the Nigerian National Code make this a mandatory requirement for ethical conduct of the research (FMOH, 2007). An efficient ERC should review both the scientific and the ethical components of the plan. Researchers derive numerous benefits from the review process including constructive feedback that will improve the research methodology, identification of and prevention of potential sources of abuse of research participants and researchers, fulfillment of the requirement for release of funds by research sponsors and publication of research findings in journals.

Despite these benefits there are a few challenges involved in the review process including delay in commencement of the research, lack of capacity of ERC to adequately monitor implementation of approved research and multiple review of same protocol by different ERC when research are expected to occur in multiple sites. In spite of these challenges, experience shows that the review is of immense benefit to researchers, participants, institutions and science.

Data Collection: Research is a serious business and responsible researchers are expected to conduct their investigation with the highest level of responsibility. They should avoid negligence and carelessness to that undermine the goals of science and ethics. Researchers are also expected to pay attention to all details before, during and after data collection. In addition, researchers are expected to implement the study as approved by the ERC and as stated in the contract agreement if the research is funded. Researchers are also required to train personnel who will collect data on their behalf to prevent injuries or harm to study participants and provide adequate supervision to trained staff to ensure that data collected are reliable, and render an account for grants or funding received.

Analysis and Interpretation of Data: One of the ethical obligations of responsible researchers during this phase of research is to analyze the data collected using the most appropriate methods to arrive at valid conclusion. The researcher must carefully select the method of analysis to prevent the occurrence of avoid Type 1 error which occur when a conclusion is reached that there is an effect between two variables when there is actually none. Appropriate analysis is also required to avoid Type 11 error, a satiation when a researcher concludes that there is no relationship

between two variables when there is actually one. In addition, the researcher is required to store all primary and secondary data in secure and accessible form, have them documented and archived for a substantial period. For example, the Nigerian National Code requires that researchers store their data for a minimum of five years post completion of the research (FMOH, 2007). Researchers also need to restrict access to data and allow only co-investigators, ERC, sponsors of research to have access to the data as part of efforts to ensure confidentiality of the data collected. Researchers can use password protected computers to restrict access to electronic data.

Report Writing: The full report of the research must be written as soon as the analysis and interpretation of the data are completed. In writing the report, researchers must present the data as collected and include as authors only those who deserve it. According to the International Committee of Medical Journal Editors, an individual deserves to be an author of a scientific publication if he/she has made substantial contributions to the development of a research protocol, implementation of the research, analysis and interpretation of the data and writing of the manuscript such that he/she can claim responsibility for the contents of the paper (<http://www.icmje.org>). In writing the report, researchers should acknowledge individuals and agencies through citations of authors, funding Agencies and others who provided assistance during the research.

Dissemination of findings: Except they are disseminated research findings may not be useful to individuals and the communities where such research is conducted. At a minimum, researchers must disseminate to the population from whom data were collected using the most appropriate channel. Equally important is the requirement that data should be disseminated as soon as they are available to ensure their timely use. Timely dissemination also creates opportunity for researchers to earn the recognition that they deserve for

conducting the research. Responsible researchers should avoid the practice of 'gift authorship' a situation where someone is listed as an author who has not fulfill the requirements for authorship.

CONCLUSION

Research is a systematic planned activity and researchers should conduct it responsibly ensuring that both goals of science and ethics are attained. Ethics has important roles to play in all the phases of research. Researchers have an ethical obligation to conduct research with the highest degree of responsibility..

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