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Informed Consent Form: Examining the challenges of obtaining Informed Consent in Legal Research in Nigeria.

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Abstract

A Consent Form is a document that is signed by a person or on behalf of the person whom they are guardian to show that they are in agreement with the consent of the document. It has been observed that many law students do not carry out proper research in the field of law and this could affect the credibility of degrees and certifications obtained in Nigerian institutions both home and abroad. This is why the scope of this paper is to understand how consent forms are obtained or used and its challenges during legal research. One of the problems a legal researcher faces while conducting legal research in any field of law is obtaining informed consent form research participants. This is why many legal researchers prefer the qualitative method of data collection which merely involves the use of the library and the internet. For the purpose of this research paper, the concept of an informed consent form, the purpose, mode of obtaining consent and challenges would be examined. This research paper would use the mixed method of research which involves the use of questionnaires, the library and the internet as sources of data collection. This non doctrinal approach aims to understand why legal researchers in various field of law don't carry out mixed study and what challenges they face when such approach is used. At the end of this study, recommendations would be provided to help legal researchers carry out proper research projects in Academic Institutions in Nigeria.

Keyword: Informed Consent, Questionnaire, Legal Research, Consent From

Introduction

Historical Background

The history of research ethics can be traced to several unpleasant events which have assisted in redefining research process globally. These unethical incidents include:

Nazi Human Experimentation

Nazi human experimentation involved several unethical medical practices that characterized the Nazi regime during World War II and the Holocaust in the 1940s. During this period, many individuals, including children, were held as prisoners of war at the concentration camps established by the Nazi regime. They were subjected to various kinds of medical experiments, such as high-altitude experiments, freezing, bone and nerve regeneration, saltwater consumption, poison gas, sterilization, poison, sulfanilamide, incendiary bombs, etc. These experiments were carried out without the consent of the victims. No anesthesia was administered to relieve them of the excruciating pain of those unpatriotic medical adventures[1].

The experimentation resulted in the deaths of many prisoners who were held captive, while several others suffered various degrees of disability, ranging from emotional and psychological trauma to insanity. Members of the international community condemned these unethical medical practices. As a result, senior physicians in the Nazi regime were tried for offenses ranging from conspiracy to murder including crimes against humanity in the notable case of USA v. Karl Brant (commonly known as the "Doctor's Trial"). In that case, nine Nazi physicians were sentenced to various terms of imprisonment, while seven others were discharged and acquitted of all the charges brought against them. In addition to this laudable judicial pronouncement, the trial has also led to the development of the Nuremberg Code of Medical Ethics of 1947.[2]

The Code was designed to regulate medical research and protect human subjects against unethical research practices. Paragraph 1 of the Code established the principle of voluntary consent. It mandates that researchers obtain the voluntary consent of research participants without any deceit, intimidation, or coercion. This obligation also requires researchers to take appropriate measures to ensure that participants are adequately educated about the purpose, procedures, benefits, and risks involved in the research process. This will assist participants in

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[1] Abibu A. Obadan and C. U. Emaviwe, '*Critical appraisal of ethical issues in legal research*', International Journal of Civil Law and Legal Research 2023; 3(2): 44-50, < https://www.civillawjournal.com/ > accessed 30 March 2024.

[2] ibid, See also, Aderonke E. Adegbite Ph. D, '*Fundamentals of Legal Research and Methods in Nigeria*', 2022. Page 50.

deciding whether or not to take part in the research. The Nuremberg Code also seeks to ensure that participants are not subjected to any form of mental or physical torture. [3]

Paragraph 6 of the Code provides for the principle of benefit and harm. It states that researchers must evaluate the advantages and risks associated with research before proceeding with it. This responsibility requires researchers to put the benefits and risks on an imaginary scale to see where the scale tilts. Paragraph 9 of the Code guarantees the right of participants to withdraw from the research process. It states that participants are free to withdraw from the research at any stage if it appears that their mental and physical strength affects their ability to continue.[4]

In Europe, the thalidomide crisis took place between the 1950s and 1960s. Chemie Grunenthal GmbH, a West German pharmaceutical business, developed the drug thalidomide to relieve morning sickness in pregnant women. The medication was sold to several expectant mothers without the required examinations to ascertain its effects on unborn infants. Many children experience varied degrees of deformities arising from the administration of the medication. These deformities include loss of limbs, phocomelia, miscarriages, and stillbirth. As a result, several employees of the company were charged with murder and homicide. However, the case was eventually settled out of court after the drug company agreed to pay the sum of 100 million DM into a special foundation as compensation to the victims of thalidomide. [5]

This scandal has significantly transformed drug administration policies in many European countries. In the US, for instance, the Food, Drug, and Cosmetic Act was amended to make it mandatory for pharmaceutical companies to establish the efficacy, durability, and side effects of their products to the satisfaction of the Food and Drug Administration (FDA) before any license is issued. To ensure that specified ethical principles were followed during the testing and trial of drugs, the FDA also established the Drug Efficiency Study Implementation (DESI) programme to reclassify already-marketed medications in the United States. [6]

Tuskegee Syphilis Study (1932-1972)

The history of research ethics can also be traced to the issues surrounding the Syphilis Study conducted by the U.S. Public Health Service (USPHS) at Tuskegee between 1932 and 1972. The study involved about 600 black low-income African-Americans and was aimed at examining the

[3] ibid.
[4] ibid
[5] ibid.
[6] ibid.

natural progression of untreated syphilis in humans. It was carried out without the consent of the participants who suffer from syphilis disease. Apart from the failure to obtain consent, officials of USPHS also misled the participants to believe that they were receiving therapy for "bad blood," a term used in the native language to describe a variety of illnesses including syphilis, anaemia, and weariness. [7]

The study continued till 1943 even after the discovery of penicillin for the treatment of syphilis leading to the death of many participants while several others suffered various degrees of disability ranging from blindness to insanity. As a result, an Ad hoc Advisory panel was set up to re-evaluate the execution of the study. The panel concluded that the study was conducted without compliance with the ethical principle of informed consent. Hence, it recommended that the study should be stopped and that appropriate compensation should be paid to affected victims. The study was halted in 1973 after the U.S. government had paid millions of dollars as compensation to the families of the victims.[8]

Conceptual Clarification

Legal research involves the evaluation of legal concepts and rules to promote a logical understanding of the law. It implies the examination of legal situations, phenomena and subject-matter. Legal research also involves the process of investigating legal and non-legal rules to determine their impact on human society.[9]

Informed consent is the voluntary agreement regarding a role a person will play in a research study after they are fully informed. This agreement shows that they are willing to participate voluntarily after having a complete understanding of what the study entails, including the duration, risks, and benefits.[10]

According to Nijhawan and 10 others, informed consent is described in ethical codes and regulations for human subject's research. The goal of the informed consent process is to provide sufficient information to a potential participant, in a language which is easily understood by him/her, so that he/she can make the voluntary decision regarding "to" or "not to" participate in

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[7] ibid
[8] ibid.
[99] Abibu A. Obadan and C. U. Emaviwe,' *Critical Appraisal of Ethical Issues in Legal Research*', International Journal of Civil Law and Legal Reseach, 2023, 3 (2); 44- 50, < https://scholar.google.com. > accessed 31 July 2024
[10] Study.com, '*Informed Consent in Research, definition, importance and example*', < https://study.com/academy/lesson/what-is-informed-consent-in-research-definition-purpose.html > accessed 24 July 2024.

the research study.[11] Michael Jefford explained that to give informed consent, individuals should understand the purpose, process, risks, benefits, and alternatives to research (or a proposed clinical intervention) and make a free, voluntary decision about whether to participate.[12]

The Supreme Court of Nigeria recognised the importance of consent in the case of *Medical and Dental Practitioner Disciplinary Tribunal v Okonkwo*[13] thus: The patient's consent is paramount…the patient's relationship with a doctor is based on consensus,… the choice of an adult patient with a sound mind to refuse informed consent to medical treatment, barring state intervention through judicial process, leaves the practitioner helpless to impose a treatment on the patient.

The Appellant, Dr Okonkwo, was found guilty of professional misconduct. He had honoured the verbal and written wishes of a Jehovah's Witness patient who refused blood transfusion and consequently died during treatment. The Nigerian appellate court upheld Dr Okonkwo's appeal and the Supreme Court concurred. The apex court ruled that an adult Nigerian has a right to refuse life prolonging medical treatment, including blood transfusion. The court located that right in the constitutional right to privacy and freedom of thought, conscience and religion.

Beyond the Okonkwo case, the courts in Nigeria have not defined the limits of the duty of consent on the physician and, thus, not much information is disclosed to the patients in actual practice. While local culture and social demands may influence the actual practice of informed consent in Nigeria, the above legal ruling, like the regulations, addressed informed consent like any Western system. Analyses of medical laws in Nigeria by legal scholars also mirror closely the demands of the law in the United States (US) and Britain and cite them as precedents.[14]

The recognition of a patient's right to give consent is not unique to Nigeria. The English Common Law recognized the right of every person to bodily integrity and its protection against invasion by others. Similarly, Carloso J, in the United States case of *Scholoendorf v Society of*

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[11] Nijhawan, Lokesh P, Janodia, Manthan D., Muddukrishna, B. S., Bhat, K. M., Bairy, K. L., Udupa, N., Musmade, Prashant B, '*Informed Consent: Issues and Challenges*', Journal of Advanced Pharmaceutical Technology & Research, Jul–Sep 2013, < https://journals.lww.com/japtr/fulltext/2013/04030/informed_consent__issues_and_challenges.4.aspx > accessed 29 July 2024.

[12] Michael Jefford, '*Improvement of informed consent and the quality of Consent Documents*', The Lancent Oncology Journal, Vol. 9, Issue 5, May 2008, < https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(08)70128-1/abstract > accessed 29 July 2024.

[13] *Medical and Dental Practitioner Disciplinary Tribunal v Okonkwo* (2001) 7 NWLR (Part 711) 79.

[14] Emmanuel R. Ezeome and Patricia A. Marshall, '*Informed Consent Practices in Nigeria, Developing World Bioethics*', < https://www.researchgate.net/profile/Emmanuel-Ezeome/publication/5399304_Informed_Consent_Practices_in_Nigeria/links/5eca9791299bf1c09adcca9b/Informed-Consent-Practices-in-Nigeria.pdf. > accessed 6 April 2024.

New York Hospital,[15] stated the capacity to give informed consent thus: 'Every human being of adult years and sound mind has a right to determine what should be done to his body…' It is important for a patient/ client to be adequately informed about his/ her medical condition.

Statement of Problems

Legal Researchers mostly focus on the doctrinal approach (qualitative method) of data collection. This involves primary and secondary sources of law which is strictly library based. Some Scholars in the legal field believe that this method is not sufficient for an effective legal study as legal researchers cannot determine whether a law or statute has positive effect or negative effect on the society.

Aim

The aim is to understand the meaning of informed consent and the challenges of obtaining it from research participants while conducting mixed method study.

Objective

To understand why legal researchers do not engage in a mixed method of data collection.

To understand the challenges legal researchers face while trying to obtain informed consent from research participants.

To understand why mixed method of data collection is relevant in legal research.

Significance of the Study

This research article would help legal researchers engage in research effectively and understand hoe laws, statutes, court decisions and international treaties influence the society. Additionally, this research can help guide the Legislative arm of government in making proper laws, regulations and policies.

Thesis Statement

The challenge of obtaining informed consent makes the non doctrinal approach (mixed method) unfavourable for legal researchers. The mixed method is effective on the grounds that it enables researchers understand how laws, edits, statutes, international conventions influence the society. Also, it helps determine whether a law should be amended, repealed or re-enacted.

[15] *Scholoendorf v Society of New York Hospital* (1914) 105 N E 92.

Literature Review

According to Obadan and Emaviwe 2023, ethical concerns in legal research have generated a considerable global interest. Both researchers examined the ethical issues involved in the process of legal research and observed that, ethical norms are often overlooked involving human participants leading to potential harm on research participants and credibility of the research work. Both authors believe that the ethical principles of informed consent, voluntary participation, privacy and confidentiality must be abided by the legal researcher.[16]

Both authors in their article believe that human life is directly or indirectly shaped by the law as law is compared like knowledge which is essential an all pervasive fact of the social condition. Law itself shapes the family, religious community, scientific research on the internal network of political parties. On this ground more emphasis is laid on research ethics aimed at protecting competing interests and ensuring that information relating to research ethics as identified by both authors include informed consent, voluntary participation, balance of harm, benefit and conflict of interest.[17]

The authors provided why their research article is significant. Firstly, to strengthen the body of knowledge by expanding previous research on research ethics as it relates to legal research involving human participants and secondly, the outcome of their study would be relevant to the entire research setting particularly academic and legal research institutions.[18]

Informed Consent according to the authors is one of the founding principles of research ethics. It is a systematic process of informing participants of the purpose, procedures, benefits, risks, and funding behind a research project to enable them to make an informed decision on whether or not to participate. Both authors divided the types of informed consent into written and oral consent. In observing their opinions, written consent to them implies the endorsement of participants on a consent form and given to participants who are well educated. In the case of oral consent, this implies verbal agreement of participants to take part in a research process. This is often used on research participants who are uneducated, illiterates or cannot comprehend written information about the research.[19]

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[16] Abibu A. Obadan and C. U. Emaviwe, '*Critical appraisal of ethical issues in legal research*', International Journal of Civil Law and Legal Research 2023; 3(2): 44-50, < https://www.civillawjournal.com/ > accessed 30 March 2024.
[17] Ibid.
[18] Ibid.
[19] Ibid.

An informed consent form creates a legal position which is ofen regarded as additional evidence that the conditions of consent have been properly acknowledged and accepted. Where informed consent form is unavailable, oral consent could be obtained where a research involves video conferencing.[20]

The authors further observed that the principles of informed consent are enshrined in the Code of Professional Conduct, ethical guidelines, national and international regulations. For example, paragraph 25 of the Declaration of Helsiniki and Article 7 of the International Convention on Civil and Political Rights of 1966. The challenges obtaining informed consent identified by the authors in their research articles are: potential communication gap between the researcher and the research participants arising from high rate of illiteracy, especially among rural dwellers, the capacity of participants to give informed consent and participate voluntarily in research could also be hindered by the level of poverty, hunger, access to healthcare and unemployment.[21]

Nijhawan and 6 others 2013 focused on the issues and challenges surrounding informed consent. Despite the authors being pure science researchers, their article is similar on the grounds that the principles, definitions, challenges and samples of informed consent form was extensively discussed.[22]

According to the authors, the goal of the informed consent process is to provide sufficient information to a potential participant, in a language which is easily understood by him or her, so that he or she can make the voluntary decision regarding "to" or "not to" participate in the research study.[23]

From the opinion of the research authors, informed consent is not only required for clinical trials but is an essential prerequisite before enrolling each and every participant in any type of research involving human subjects including; diagnostic, therapeutic, interventional, bioequivalence, social and behavioural studies and for all research conducted domestically or abroad.[24]

One unique aspect of this research article is that its main focus was on the issue of informed consent and it discussed on the basic elements for written informed consent documents,

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[20] Ibid.
[21] Ibid.
[22] Nijhawan, Lokesh P, Janodia, Manthan D., Muddukrishna, B. S., Bhat, K. M., Bairy, K. L., Udupa, N., Musmade, Prashant B, '*Informed Consent: Issues and Challenges*', Journal of Advanced Pharmaceutical Technology & Research, Jul–Sep 2013, < https://journals.lww.com/japtr/fulltext/2013/04030/informed_consent__issues_and_challenges.4.aspx > accessed 29 July 2024.
[23] Ibid.
[24] Ibid.

requirements for obtaining informed consent, tabular analysis of informed consent process flow, waivers to informed consent and the challenges in informed consent process.[25]

In discussing the challenges in informed consent process, the authors identified the following: language barriers, religious influence, false expectation, patient perception, children and vulnerable groups. Finally, the researchers used an illustration in India to create a picture of the challenges and communities before engaging in clinical trials.[26]

CONCEPTUALIZATION

Informed consent remains one of the building blocks of a successful research process. Its implication has been impeded by several social, cultural and economic factors that are capable of compromising the voluntariness of consent. These challenges include but are not limited to the potential communication gaps between researchers and participants arising from the high rate of illiteracy mostly from rural dwellers. The capacity of participants to give informed consent and participate voluntarily in research could also be hindered by the level of poverty, hunger, access to health care and unemployment that prevails in a particular society.[27]

Apart from the challenges identified above, Nijhawan and six others 2013 gave their own views on the challenges of obtaining informed consent generally. Firstly, language barriers have been a challenge in a multilingual society. The view point of the authors is that many participants fill informed consent forms without proper understanding which sometimes lead to redrawal of research process in later stage. The authors believed that research have the duty to ensure that participants fully understand the content of an informed consent form.[28]

Secondly, religious influence also plays a role in influencing the thoughts and believes of a research participant. The authors are of the opinion that there is a conflict between research methodology and rules of behaviour set by a participant's religion. Religion could hinder a participant from achieving full result of findings during legal research.[29]

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[25] Ibid.
[26] Ibid.
[27] Nijhawan, Lokesh P, Janodia, Manthan D., Muddukrishna, B. S., Bhat, K. M., Bairy, K. L., Udupa, N., Musmade, Prashant B, '*Informed Consent: Issues and Challenges*', Journal of Advanced Pharmaceutical Technology & Research, Jul–Sep 2013, < https://journals.lww.com/japtr/fulltext/2013/04030/informed_consent__issues_and_challenges.4.aspx > accessed 29 July 2024.
[28] Ibid.
[29] Ibid.

Thirdly misunderstanding can still occur due to participants false expectations of the experiment outcome. It is observed that participants may hide their true intentions in other to produce false results which can negatively affect the outcome of a research.[30]

Additionally, the participation of a patient is very difficult to deal with. According to the authors, an example was given of a case where participant prefer traditional health treatment to western medical treatment. The authors in their article warned researchers to be careful not to give too many details which could scare participant away.

RESEARCH METHODOLOGY

The research method adopted in this article is the Non- Doctrinal Approach of data collection which goes beyond the library but into the field to obtain data. This method includes the use of the library, internet research and the use of questionnaires in other to understand the view point of research participants. Questionnaires drafted from the Google form platform is been used and the website link is sent to Whatsapp online group chat for legal practitioners and committee group chat of the Nigerian Bar Association.

LEGAL ANALYSIS

The following analysis was produced form the Google form platform.

88% of Lawyers from a population of 26 have engaged or are currently engaging in a legal research. The research participants further provided answers on where their research was conducted such as in academic institutions, at a work place etc. On the type of method used by the participants, 70.8% believed they used the non doctrinal mixed method, 12.5% believed they used the non doctrinal qualitative method and 16.7% believed they used the doctrinal qualitative method. In other to understand how well the participants understand the mixed method, 63.6% believed that they used the library and internet sources while 36.4% believe that they used various sources such as the internet, library, questionnaire etc. On why the mixed method was not used, the major reason is because the method was not compulsory.

77.3% of the participants chose the yes column that the mixed method was an option which in this case means that Law researchers are at the liberty to use any research method available to them. 66.7% believed that their research supervisors encouraged them in using mixed method of research while 33.3% of the participants were not encouraged by their research supervisors. 88.3% believed that they did not draft an informed consent form while 16.7% drafted. 60%

[30] Ibid.

obtained oral consent while 40% obtained consent through other means. This could be, by written forms. 90.5% believed that the mixed method form of research yielded positive results as compared with 9.5%. Statistical data is hereby provided below.

Diagram 1.1

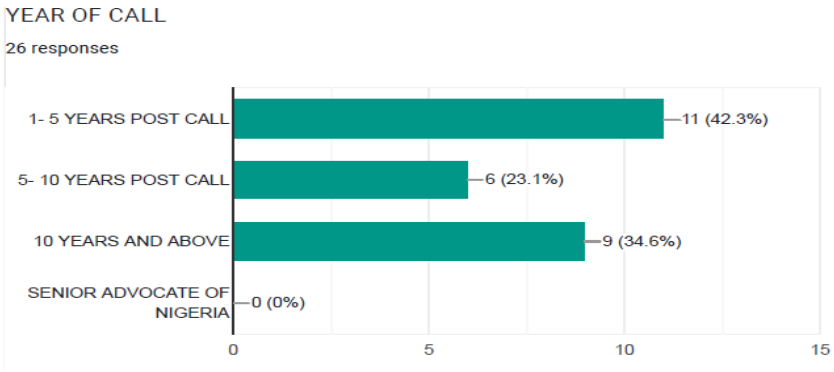


Diagram 1.2

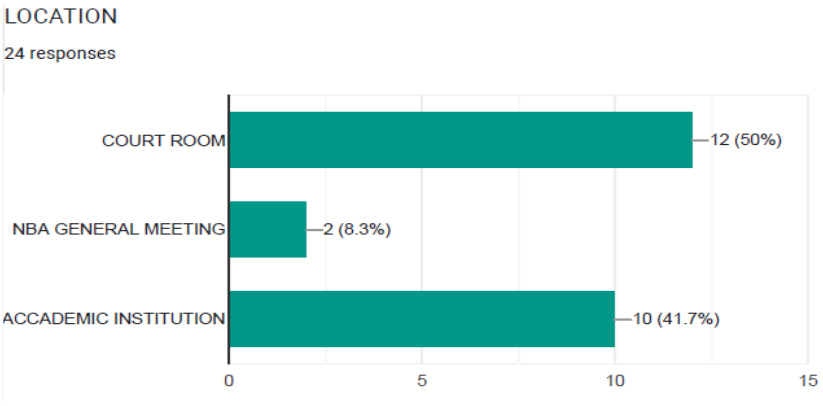


Diagram 1.3

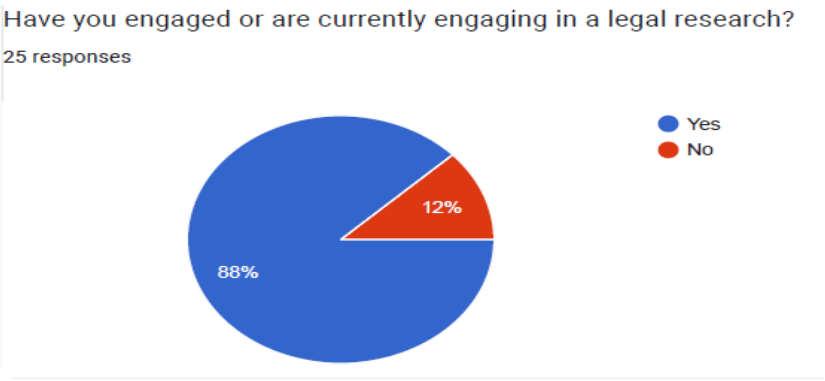


Diagram 1.4

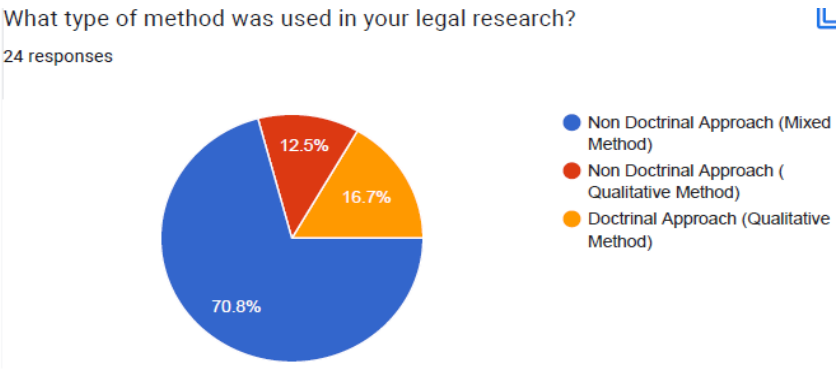


Diagram 1.5

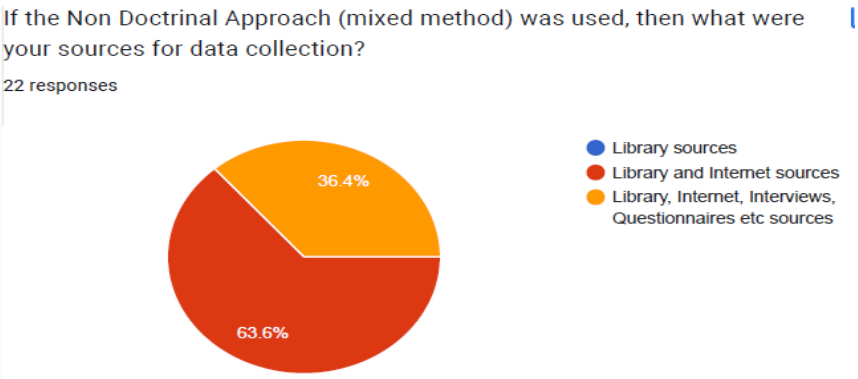


Diagram 1.6

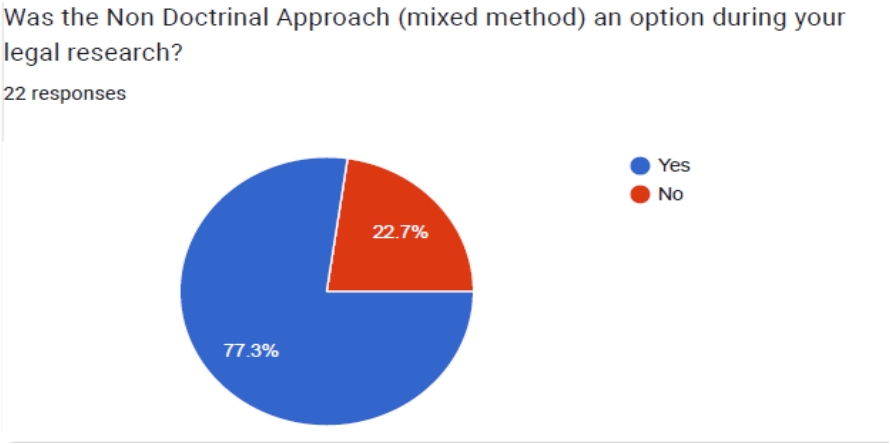


Diagram 1.7

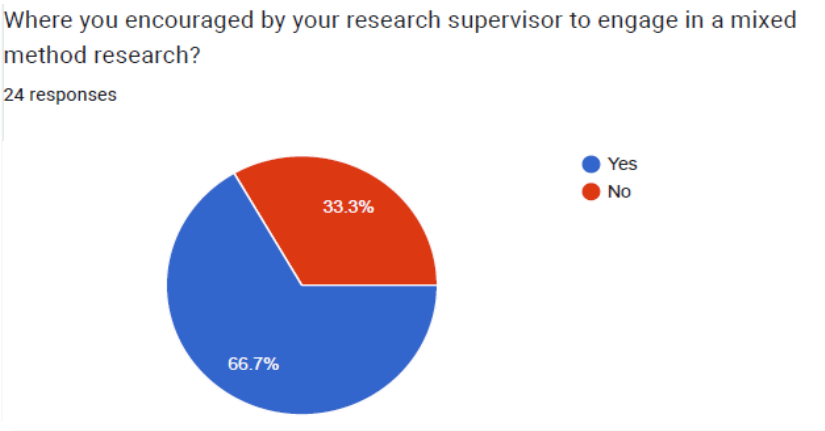


Diagram 1.8

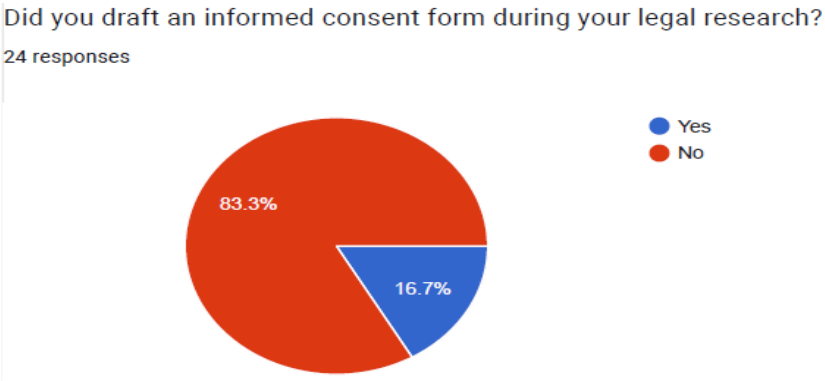


Diagram 1.9

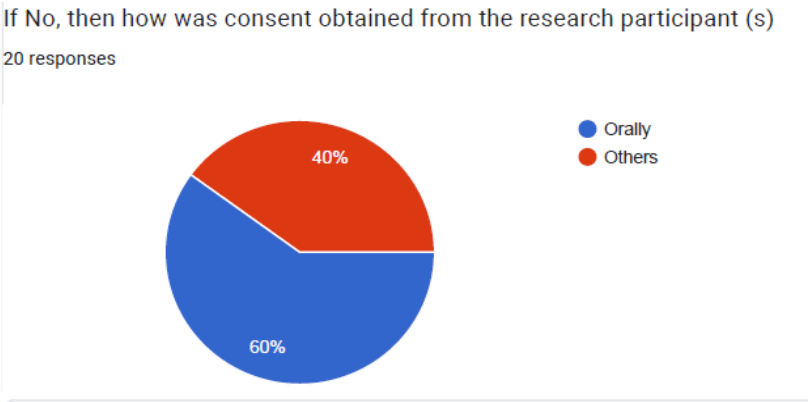
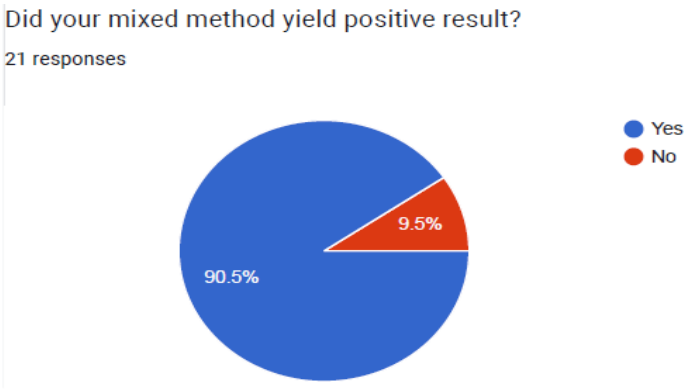


Diagram 1.10



CHALLENGES USING THE GOOGLE FORM QUESTIONNAIRS PLATFORM

A link was generated from the Google Form online application and then copied and pasted on the Whatsapp and Telegram group chat Application for lawyers for the Nigeria Bar Association Lagos Branch, the Human Right Committee Lagos Branch, and Class room group chat for Lead City University Postgraduate Students. A population of 50- 100 participants was needed but only 27 persons participated in the research questionnaire. The major reason given was fear of cyber fraud and internet scam which is very popular in the Nigerian society. The main advantages of using the Google Form platform is that it reduces paper and transportation cost.

The statistical analysis of the questionnaire was provided in PDF format.

SUMMARY, CONCLUSION AND RECOMMENDATION

The history of informed consent could be traced to unethical practices during the Nazi's German experiments on humans during the Second World War. As a result of this unethical behaviour Nazi physicians were tried for criminal offences and crimes against humanities in the popular case of USA v Karl Brant commonly called the Doctor's Trial. The end of the trial led to the development of the Nuremburg Code of 1947. Another history of informed consent could also be traced to the Tuskegee Syphilis of 1932- 1972.

In legal research, informed consent is a voluntary agreement regarding a role a person will play in a research study after they are fully informed. Informed consent could be obtained orally or in writing. Where informed consent is in writing, an informed consent form would be drafted and signed by the research participants.

The aim of the research article is to understand the meaning of informed consent and the challenges of obtaining it from research participants while conducting a mixed method study to ensure that legal researches are properly conducted.

The challenges of obtaining informed consent as identified in this article are language barriers, religious influence, false expectation, patient perception, illiteracy and capacity of participants. The mixed method study was used during the research and this included the use of library, internet sources and the use of Google form questionnaire.

In conclusion, in an estimated population of 50 lawyers, only 27 participated using the Google form questionnaire link and the analysis were provided in PDF format.

RECOMMENDATIONS

After an indebt analysis of the Google form questionnaire, the following are hereby recommended: Firstly, lawyers need to be well trained and educated in research methodology. Most lawyers after their law school graduation do not proceed for post graduate training programmes. They become more focused library and internet based methods. This method may not be appropriate for certain fields in the legal profession.

Secondly, research supervisors need to encourage their law researchers in engaging in a mixed method. From an analysis of the Google form questionnaire, 66.7% of research participants were encouraged to engage in a mixed method as compared with 33.3% of participants who were not encouraged by their supervisors.

Thirdly, law researchers are advised to draft informed consent forms while conducting interviews. Interviews could be conducted on mobile devices though phone calls or social media applications such as Zoom virtual, Skype, Whatsapp, and Google meet etc. One main advantage is that it protects confidential information between the lawyer and the research participants.

Fourthly, law researchers need to learn how to us Artificial Intelligence (A.I) tools due to its growing influence in the legal profession. Artificial Intelligence tools research for example Copilot, Cotana, Chat GBT and Google A. I. An example is the ability of a law researcher in drafting an informed consent form and questionnaire which could be sent t the email of the research participants. This new technology is becoming dominant considering the fact that potential participants have access to smart phone devices.

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6. Emmanuel R. Ezeome and Patricia A. Marshall, '*Informed Consent Practices in Nigeria, Developing World Bioethics*'.

LIST OF CASES

1. Medical and Dental Practitioner Disciplinary Tribunal v Okonkwo (2001) 7 NWLR.
2. Scholoendorf v Society of New York Hospital (1914) 105 N E 92.

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8. Diagram 1.8
9. Diagram 1.9
10. Diagram 1.10