iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 13 **Issue:** IV **Month of publication:** April 2025

DOI: https://doi.org/10.22214/ijraset.2025.69508

www.ijraset.com

Call: 08813907089 | E-mail ID: ijraset@gmail.com

International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue IV Apr 2025- Available at www.ijraset.com

Ethical Consideration in Clinical Trials

Ms. Shweta Navale[1], Ms. Rekha Kolape[2], Mr. Nitin Gawai[3], Mr. Vijay Dabade[4], Ms. Sarika Lakade[5]
B.Pharmacy Department, Mahadev Kanchan College of Pharmaceutical Education & Research, Uruli Kanchan, Pune, Maharashtra, India

Abstract: ***Ethical considerations are crucial in clinical trials and drug testing, safeguarding the welfare and rights of Participants are safeguarded. Essential principles encompass voluntary involvement, informed agreement, reducing harm, and promoting equitable choice of participants. Research should focus on both social and clinical significance, as well as scientific Validity and consideration for participants. Clinical research is vital in the provision of health care. It is via Clinical research involves scientists creating new therapies, cures, and preventive strategies that assist in managing the Transmission of illness. Additionally, clinical research guarantees that, as these therapies are introduced to the market, they have been demonstrated to be safe and effective, with any possible side effects revealed. Clinical studies are essential in the progress of medical science and the creation of new therapies. Nonetheless, guaranteeing ethical behavior throughout the research process, it is crucial to safeguard the rights, dignity, and welfare of participants. This The review article examines the fundamental ethical principles that regulate clinical trials, such as informed consent, risk-benefit evaluation, confidentiality, and fair selection of participants. It also explores global Standards including the Declaration of Helsinki, the Belmont Report, and Good Clinical Practice (GCP) Criteria. Issues like at-risk communities, the use of placebos, and ethical dilemmas in emerging nations are examined. The article highlights the significance of institutional review boards (IRBs) and continuous ethical Oversight to uphold public confidence and research credibility. Through the examination of previous cases and ongoing practices, this review emphasizes the importance of ongoing ethical attention in the swiftly changing field of clinical research.***
Keywords: Clinical Trials, Ethics, Informed consent, Risk and benefits, placebo.

I. INTRODUCTION

The phrase clinical research does not exclusively refer to studies related to a new medication/clinical Item. It pertains to all forms of research that involve the involvement of human participants. The procedure needs to Also include the name, title, and contact numbers of the medical professionals appointed by the Sponsor, the

Researchers leading the study, the Names location, and the contact information for the study centers. The protocol must include details about the possible expected risks and the advantages of conducting the study. To carry out clinical research with an investigational new product or drug, the sponsors/ Researchers need to validate the study and establish the goals. The research should account for everything the ethical standards established by both local and international regulatory bodies. The backer and the Researchers must ensure the rights of the participants are upheld. Additionally, they need to guarantee that the device Guidelines for selecting participants, the criteria for exclusion, and the conditions for voluntary involvement and Removal of the participants at any moment throughout the study, securing informed consent. The new investigational the investigational brochure outlines that the drug (IND) must be handled and stored with care. The IND needs to be properly assessed for its resemblance to an existing medication, the pertinent pre-clinical Information that backs the goals and purposes of the research. A properly organized protocol leads to achievement. Clinical studies [1] The ethical integrity of a clinical trial is not concluded with the creation of the study design and a signature on the Consent form for information. Safeguarding the rights, interests, and security of research subjects must persist, during the entire period of the study. Monitoring the safety of subjects is the duty of various teams, including research ethics boards (REBs) or institutional review committees (IRCs), researchers and their research teams, sponsors and data oversight groups (DMCs), also referred to as data and safety oversight boards (DSMBs), particularly in the U.S. Accounts over the past few years regarding the fatalities of research participants and Shortcomings in the oversight of clinical trials have generated substantial apprehensions about the systems and procedures. through which participant safety is presently overseen The unforeseen disastrous negative incidents in a "first-in-human" The "trial" of a medication known as TGN1412 raised ethical concerns regarding the design of clinical studies and the monitoring of safety. Notwithstanding the results of the Medicines and Healthcare products Regulatory Agency (MHRA) inquiry, which identified no link between the negative events and drug administration, worries persist about if the medication was given to the participants in less time than the approved duration (20 minutes) instead of 2 hours) and whether the pharmaceutical company ought to have anticipated that the medication would cause the disastrous responses observed in individuals

©IJRASET: All Rights are Reserved

[2] This will result in ongoing revisions of guidelines, creating new guidelines, suggesting new policies, and Implementing suitable regulations, ensuring that human research participants and the community feel confident that They are securely safeguarded during their involvement in any research activities. [3] Experiments involving patients like incarcerated individuals who were compelled to take part, or research conducted in underdeveloped nations. Have been criticized for lack of sufficient external oversight. Even though a constant state of alertness is necessary the ethics of current clinical trials is primarily limited to the creation and execution of the protocol due to the outcomes can be significantly affected by seemingly trivial aspects. [4]

A. History of ethical Issues and Clinical Trials

History contains many unethical medical experiments, especially the infamous Nazi tests recorded in the Nuremberg trials. Nonetheless, the exploitation of human subjects also took place in other nations. For instance, dating back to 1932 until the 1970s, the US Public Health Service studied hundreds of men with syphilis to understand the disease's natural progression. Course of the illness, and persisted with the research even after penicillin had proven to be a successful treatment (Curran 1973). In 1963, the American Cancer Society and the US Public Health Service endorsed a study of Cancer immunotherapy involving the injection of viable cancer cells into 22 elderly, frail individuals without sufficient informed consent (Katz 1972). Between the 1950s and the 1970s, researchers studying a hepatitis Vaccine-administered live hepatitis virus to children residing at the Willowbrook State Hospital in New York without Adequate informed consent (Krugman et al. 1967). Besides these noted instances, Beecher (1966) Recorded further ethically questionable research [5] The Declaration of Helsinki, released by the World Medical Association in 1964, has been updated and is now recognized as an ethical standard in medical research involving humans. The significant alterations in the most recent Revision published in 2013 addresses compensation for injuries related to clinical trials and the approval of placebo use. Clinical studies, safeguarding at-risk groups, and post-research support [6]

B. The role of research in ethics committee

In their work "Research Ethics Committees and Paternalism," Edwards, Kirchin, and Huxtable advocate for a robust approach to consent. Oriented perspective on the function of the REC. They claim that while non-competent research participants might require. The situation of capable individuals does not justify this paternalistic stance despite the REC's protective measures. It seems like your request is incomplete. Please provide the complete text you would like me to paraphrase. In my opinion, the REC's function in relation to competent authorities should adhere to the boundaries established by public policy, which Participants provide authentically valid consent to take part in the research at hand. This indicates that a study the ethics committee's responsibilities may conclude after they have asked a researcher to present a precise declaration. Concerning dangers in the patient information document. Somewhat unusually, Edwards et al propose that when The REC believes the Research carries unnecessary risks; such a statement should also be included on the sheet. [7] The committee ought to oversee the research process, and the researcher must supply essential Data when asked by the committee. In the event of protocol breaches or negative incidents happening during the study, they need to be reported to the committee as per the set regulations [6]

II. TYPES OF CINICAL TRIALS

1) Therapeutic studies: Evaluate experimental therapies, novel drug combinations, or innovative methods of surgery or radiation treatment.
2) Prevention studies: Seek improved methods to avert illness in individuals who have never experienced the disease or to stop a disease from coming back. These methods might encompass medications, vitamins, immunizations, minerals, or changes in lifestyle.
3) Evaluative tests: Performed to discover improved tests or methods for identifying a specific disease or condition.
4) Screening studies: Evaluate the most effective method for identifying specific diseases or health issues.
5) Standard of Living: Studies (or Supportive Care studies) investigate methods to enhance comfort and the overall quality of life for people with a long-term sickness [8]

A. Supervising clinical trials:

The aims of trial monitoring are to ensure that:

- The rights and welfare of human participants are safeguarded.
- The trial data that has been reported is secure.
- The trial is being conducted in accordance with the presently approved protocol/amendment(s) and GCP, as well as In accordance with the relevant regulatory requirement(s) [8]

ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue IV Apr 2025- Available at www.ijraset.com

III. KEY ETHICAL CONSIDERATIONS IN CLINICAL PRACTICE

A. Informed Consent

The informed consent process encompasses how information is presented to patients and the methods of Acquiring written consent can differ based on particular country circumstances; for instance, the degree of literacy, Grasp of the scientific problems and structure of the community. The circumstances could affect the Approval processes, especially when at-risk groups are enlisted in a clinical study. The participation of Individuals familiar with the local socioeconomic settings, cultures, and traditions capable of safeguarding the interests of individuals impacted by the trial must be considered to ensure the best possible informed consent. Protocols for possible participants in a clinical study [9] Thus, honoring patient autonomy within the realm of clinical practice and research necessitates incorporating Patient choices and values in decisions regarding treatment options, care objectives, and assessment of Optimal welfare, and involvement in research studies and clinical trials. The procedure of willing and knowledgeable Consent is rooted in maintaining patient autonomy; without it, there is a danger of decisions being made that Contradict patient preferences and thereby undermine a patient's autonomy is sharply intensified. The principle of Informed and voluntary consent in clinical medicine and research was established in the Nuremberg Code, Belmont. Report and Declaration of Helsinki, further solidified in definitive writings by bioethicists and ethical scholars. Thinkers, such as Beauchamp and Childress' Principles of Biomedical Ethics [10]

B. Risk and Benefits

Clinical research can only take place when the research aim surpasses the risk associated with the study. Participants. All clinical trials must take place only after a comprehensive assessment of the possible risks and Advantages for the research subjects. Researchers ought to develop strategies to mitigate the dangers and also must consistently observe and document the risk factors. If it is concluded that the danger surpasses the possible Advantages of the research, or if a notably negative occurrence or danger is identified, it must be communicated to the study Ethics committee to determine if the study plan should be modified or terminated [6]

C. Data Safety Monitoring Boards (DSMBs)

The creation of DSMBs stemmed from the acknowledgment in the 1960s that autonomous methods of provisional the tracking of gathered data was crucial for assessing the continuous safety of subjects in a trial. Fundamentally, Individuals deeply engaged in trial design and execution may lack complete objectivity when assessing interim data. For new issues regarding risks to trial participants. To ensure the required oversight, DSMBs typically Comprise Individuals with relevant knowledge in the disease being examined, along with statisticians, ethicists, and occasionally community delegates [2]

Determining the Need for a DSMB

Every clinical trial necessitates a safety monitoring plan, though not all trials need an external formal committee to. carry out the Monitoring. The aspects to take into account when assessing the necessity for a DSMB mainly concern Security, practicality, and scientific credibility (refer to FDA Guidance Clindatmon, pdf), as detailed in Table 1. These Criteria clarify the reasoning for the National Institutes of Health's (NIH) mandate that a DSMB must be established. set up for all phase III trials and a Safety Monitoring Plan for phase I and phase II trials. The FDA mandates a DSMB for extended trials with mortality or significant morbidity outcome measures, when serious adverse events are anticipated, with new and/or possibly high-risk therapies, when there is minimal prior knowledge about the treatment being studied. is accessible, When examining a highrisk group made up of sensitive individuals (e.g., seniors or children) patients), or in a multicenter or extended study. On the other hand, an external DSMB is unnecessary during the early phase. studies (excluding gene therapy studies), studies focusing solely on symptom endpoints, and brief studies[2]

IV. ETHICAL PRINCIPLES

A significant portion of the ethical examination concerning global research has concentrated on the responsibilities of researchers and Sponsors once sites have been chosen. Suggestions frequently appear as, 'If you position your research here,' Wherever 'here' might be, 'these are the ethical responsibilities, challenges, and factors that pertain.' Conversations Have tackled, for example, access to medications after trials for communities and individuals involved in studies, Obstacles and enablers for acquiring quality informed consent globally, acceptable levels of care for Comparator agents in randomized controlled trials and challenges in research capacity and regulation, among others Concerns [11]

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

A. *Use of placebo*

An initial problem related to the use of placebos involves the issue of misleading patients. Patients in the placebo group of a Clinical trial participants should be convinced that they are receiving an effective treatment, even if they are not, for the Placebo effect to have any influence whatsoever. Notwithstanding the appearances, it remains debatable that placebo-controlled Trials (PCTs) are fundamentally misleading to participants. This is due to Participants are indeed made aware, upon consenting to the study, that they will not be informed whether they are Administering either active medication or a placebo [12]

The Helsinki declaration indicates that a placebo should only be administered when effective medications are unavailable for a specific condition. Sign. Nonetheless, this ethical obligation is often overlooked in various situations. For example, during tests involving an In the add-on design, one of the arms gets the new drug and the other one receives a placebo, while both are administered an An effective medication that is currently accessible which, therefore, cannot be excluded; this is permissible if there is no Previous research indicating that a different medication has already demonstrated a positive impact for the same purpose with the Identical layout. The RCTs of novel antiTNFa or other drugs known as disease-modifying anti-rheumatic drugs (DMARD) Is paradigmatic: they are combined with methotrexate in contrast to placebo despite other medications being already recognized to work synergistically with Methotrexate. An additional instance is in diabetes. Exenatide has been shown to be more effective than placebo in patients receiving a glitazone and metformin for reducing fasting Plasma glucose and glycosylated hemoglobin (Hb A1c) This structure has revealed diabetic patients who were treated with Placebo to ineffective risk. An equitable comparison would involve utilizing one of the numerous antidiabetic medications accessible. Available in the market rather than a placebo [4]

B. *Inclusion and Exclusion Criteria*

The eligibility requirements for the majority of RCT favor young males. Women, children, and older adults are S. Garattini, V. Bertele' / Journal of Hepatology 51 (2009) 792–797 793 Often omitted from RCT due to they present challenges regarding their susceptibility to negative responses. Nevertheless, older individuals specifically are the those obtaining the most drug prescriptions. Rochon et al. discovered that among 9,664 patients in the RCT addressing among those with osteoarthritis and rheumatoid arthritis, only 2.1 percent were over 65 years old, with just 14 patients being older. more than 75 years. In a Health Technology Assessment report regarding the application of bevacizumab and cetuximab in for metastatic colorectal cancer, the included patients were 5–10 years younger than the corresponding UK population. Illness, casting uncertainty on the applicability of the findings. Comparable thoughts apply to children, who are typically administered with dosages modified based on body weight determined in studies conducted on adults, overlooking the the reality that a developing body exhibits responses that may differ from those of adults. It is concerning to think that approximately 50 percent of medications currently given to children or adolescents have never been examined in a randomized controlled trial. [4]

C. *Investigators*

Similar to study sponsors, investigators and their research teams have a broad array of responsibilities that encompass following the Protocol study framework, performing an ethically sound informed consent procedure, guaranteeing data accuracy, preserving the necessary document files, and providing explanations of AEs within the framework of familiar information regarding the intervention As people on the "front line" of the research effort, Investigators and their research teams are responsible for ensuring the correct implementation of the inclusion/exclusion criteria, The correct management of study interventions, along with precise monitoring and documentation of adverse events. Every one of these activities have significant consequences for the safety of subjects [2]

D. *Foreign Clinical Investigations*

The FDA allows the use of international clinical study data to back a marketing application. Authorization of a human apparatus. It is the duty of the foreign manufacturer to make certain that the foreign clinical Data provided to the FDA are: relevant to the US population and US medical practices, that the clinical The investigation design aligns with the FDA's scientific criteria (e.g., stipulations for statistical analysis), ensuring that the clinical Investigators have acknowledged the capability, and the FDA can authenticate the information through on-site evaluations. Examinations or other suitable assessment actions [13]

V. ETHICAL ISSUES IN EPIDEMIOLOGY AND PUBLIC HEALTH PRACTICE

The findings of epidemiological research contribute to broadly applicable knowledge by clarifying the reasons of illness; by integrating epidemiological data with insights from other fields like genetics and microbiology; by assessing the alignment of epidemiological information with causal theories; and by establishing the foundation for creating and assessing health promotion

ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue IV Apr 2025- Available at www.ijraset.com

and prevention strategies. It seems that your input was incomplete. Could you please provide the full text you'd like to have paraphrased? The main professional responsibilities of epidemiology involve the planning and execution of scientific studies and public health initiatives, application of scientific knowledge in healthcare. This involves documenting research findings and upholding and enhancing wellness within communities. In executing these professional responsibilities, epidemiologists frequently come across a numerous ethical dilemmas and concerns that necessitate thoughtful reflection. Numerous problems have been discussed in the literature concerning ethics in epidemiology and public health practice, including ethical guidelines. [14]

A. Ethical Issues in Screening

Moral dilemmas also emerge in public health screening initiatives. Screening involves the initial identification of an unidentified illness or disorder through the application of tests, assessments, or various methods that may assist in recognizing a illness indicator in seemingly healthy individuals. Individuals with affirmative or questionable results subsequently go through Additional assessment or care. The primary goal of screening is to lessen the illness or death from a condition within the individuals examined. Numerous frameworks for evaluating and tackling ethical and policy concerns in public health, proposals for screening programs have been made. In 1968, Wilson and Jungner put forward 10 principles. For widespread testing initiatives [14]

B. Ethical Considerations for Human Genetics and Genomic Research

The clinical research related to the human genome involves both risks and benefits, as well as confidentiality. Concerns, caregivers, infants, minors, and undisclosed Testing for hereditary conditions. Upon finishing the in the year 2000, scientists gained an enhanced understanding of human genome sequencing for the first time. The origin of numerous illnesses. This has set the stage for the creation of rules that regulate Scientists/researchers who conduct genetic mapping and genetic evaluations. With enhanced understanding of in the field of human genetics, researchers have been working on treating and preventing genetic disorders through gene therapy (somatic). Cell gene treatment, germline treatment). This has raised ethical issues globally, and the Regulatory authorities ensure that this therapeutic method is not exploited and remains accessible. To every person regardless of their economic condition. Multiple gene banks and cell line collections have begun to function by gathering human Genome/DNA/tissue/cord blood for potential future utilization. The Collections may consist of two Kinds: the unknown samples, as well as the recognized samples/collections. The samples might also be gathered. Solely for research purposes and are identified as anonymous samples, unconnected samples, and coded samples. Genetic research adheres to the same ethical principles as other forms of clinical studies, where the rights of participants are granted higher importance. Additionally, genetic research focuses not only on the people as well as with their families and the community/society. As a result, extra attention is given to tackle ethical issues to prevent physical and psychological harm, as well as harm to family relationships. [2]

C. Ethical Challenges in Clinical Research During the COVID19 Pandemic

COVID-19 Pandemic and Clinical Trials: Coronavirus Disease 2019 (COVID-19), the expression of the illness Triggered by the SARS-CoV-2 virus, was initially reported in December 2019 as a pneumonia outbreak in Wuhan, China and quickly disseminated across the globe. On January 30, 2020, the World Health Organization (WHO) Proclaimed COVID-19 a Public Health Emergency of International Concern (World Health Organization 2020), and on March 11, 2020, the WHO announced it a pandemic (Branswell and Joseph 2020). As of May 12, 2020, there exists There are more than 4.2 million confirmed infections (COVID-19 Dashboard 2020) and more than 290,000 fatalities due to the illness, And more than 1300 clinical trials regarding “COVID-19” or “SARS-CoV-2” cataloged on Clinicaltrials.gov, where 783 are Interventional trials comprise eighteen, while seventeen are expanded access studies (ClinicalTrials.gov 2020). On the first of May in 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for remdesivir, a Nucleoside ribonucleic acid (RNA) polymerase blocker, intended for the management of hospitalized individuals suffering from COVID-19 (Remdesivir EUA Authorization Letter 2020). However, prioritizing trials, deciding which trials to start, persist, stop and restart, represents a continuous and developing ethical dilemma [15]

D. Navigating ethical challenges of conducting randomized clinical trials on COVID-19

Difficulties in establishing priorities for the research agenda on CVID-19: Significant deficiencies exist in our current understanding of COVID-19, yet the illness poses serious health and social challenges, and financial repercussions, rendering it essential to perform scientifically sound clinical studies assessing possible preventive measures, alleviating therapies, and supportive care alternatives [1, 6].

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

The immediacy for Despite rapid progress in COVID-19 treatment, there is a moral obligation to secure informed, approval for involvement in such RCTs. In the realm of clinical research on COVID-19, numerous factors arise moral dilemmas regarding the implementation of trials [16]

VI. SPECIFIC ETHICAL ISSUES

A. Research Design and Ethics Review

A highly debated topic regarding the execution of clinical trials in developing nations is whether the control group has to undergo the same intervention as what would be administered if the research, were carried out in an advanced nation. For instance, studies that evaluated a brief treatment with zidovudine with placebo for preventing perinatal transmission of human immunodeficiency virus (HIV) infection generated significant debate. It is already established that an extended course of zidovudine decreased perinatal transmission,20 prompting some to contend that The employment of a placebo in following studies was considered unethical.19 In our perspective, a trial intervention should typically be compared with a recognized, effective therapy (defined as a therapy that has broad recognition by the global medical community and that is as efficient as any other option. therapy for the illness or ailment), regardless of whether it's not that treatment exists in the host nation. Consequently, the assumption is that a placebo control, or any alternative method that is not as effective as a proven treatment is considered ethically unacceptable.[17]

VII. ETHICS AS A WORKABLE DOCUMENT

In reply to the revision of the Helsinki declaration, the U.S. Regulators highlighted the importance of research efficiency to researchers in the industry. And the unclear morals of The Placebo might be circumvented by supplying for what is referred to as "equivalent medication"—not necessarily the Optimal or regular therapy, but any option that is accessible as the optimal regional counterpart. "'Should I provide a sugar pill or vitamin C?' one researcher asked me with cynicism." It seems that your text is incomplete. Please provide the full text you would like me to paraphrase, and I'll gladly assist you! In the interim, the study will uphold ethical standards, the data will maintain integrity, and unfortunately, the patients will continue to receive treatment . Another investigator reflected the truth of this change. From worries regarding redistribution to those focused on efficiency Criteria in international research when he informed me that morality came to be regarded as a "viable document." "Comparable" Medications in Eastern Europe differ from their counterparts in Western Europe, which means you could operate. The "Helsinki declaration," he remarked. For the sake of efficiency, Pharmaceutical firms and CROs heightened their Look for treatment-naïve groups around the globe. In examining the connection between regulation and the establishment of ethics in human research, Marks observes, "It is It feels as though ethical discussions and the rules regulating research inhabit two separate realms that have some similarities. "Typical components yet remain unlinked" (2000:14). It appears that your input is incomplete or missing. Please provide the full text you'd like me to paraphrase, and I'll be happy to assist you! The primary purpose of this Helsinki genealogy is to illustrate how interconnected these universes are. Regulatory actions in the Context of discussions regarding the revision of the Helsinki declaration (which was, in turn, a reaction to contentious applications of Human subjects are in themselves creating new populations of Human participants—the intervention [18]

VIII. HEALTHCARE ETHICS AND GLOBAL HEALTH INEQUALITIES

Disparities in healthcare delivery, biomedical research and the need for infrastructure investment is alarmingly evident across the globe. Healthcare spending in developing nations represents under 1% of the total for OECD nations. (members of the Economic Cooperation Organization And Development).1 Global perspective on healthcare ethics Is crucial for addressing the disparities in global health. By enhancing medical research, healthcare delivery, and distribution of resources. This reform is essential. when Traditionally, a minimal portion of the worldwide disease burden has Drawn a significant amount of worldwide spending for biomedical Study.[19] informed consent procedure. Specific populations, like racial minorities and those facing economic hardships, Patients who are extremely ill and those in institutions may consistently be pursued as subjects for research, because of their effortless accessibility. The at-risk population, due to their reliance and their impaired ability for voluntary consent must be safeguarded from the risk of being. Engaged in research. [20] A research initiative in Zambia focused on evidence-based psychotherapy for children determined that: "Research documenting the processes of implementation is essential to grasping the reasons behind intervention decisions and the manner in which the adaptations are produced in worldwide mental health. Additional Articles are required on the most effective ways to apply evidence-based treatments in LMIC [21].

A. How shall we recruit patient-subjects for participation?

Participation of individual subjects necessitates their consent that is informed. One element of the broader topic of informed consent is extremely contentious and distinctly pertinent to the execution of RCTs: Is it essential to reveal to the potential patient-subject the reality that the therapy for him or her will be decided by opportunity? [22] Recruitment represents a fascinating interaction among researchers, guardians, and the offspring. Investigation inherently entails uncertainty, this suggests that trust plays a vital role in the hiring process. Every doctor and most research shown Recruiting patients for pediatric clinical trials presents significant challenges.[23] A crucial factor is that patients often Think about, when Choosing to participate in a clinical trial holds potential anticipated advantages for them. Another important element is Altruism. [24] A challenge arises from the necessity of ethics to not only perform the correct action but also to simultaneously make it correct. Adherence to a necessity (for instance, parents provided approval, the patient has been informed) is not sufficient to consider that a child's enlistment was justifiable. [25]

B. Subject Selection And Vulnerability

Equitable choice of subjects. Equitable choice of subjects is an Crucial element of ethical research that tackles The concept of beneficence (i.e., who aligns with the scientific Standards for research and those capable of acquiring Advantages of participating in research with a satisfactory Degree of danger), the concept of fairness) And the principle of honoring individuals (i.e., who is not In a vulnerable situation or easily influenced state And in what ways can vulnerability be reduced or Overseen).[26] The substance-user individuals in addiction studies Should receive these equivalent safeguards against harm and the same opportunities for research advantages as other participant groups. Nonetheless, the simple presence of ethical principles offers no assurance that they will be put into practice. Suitably, or that the expected results will be Accomplished [27] Equitable participant selection in AI clinical trials surfaced as an important issue, especially concerning the precise portrayal of the targeted patient population. Examination Participants emphasized the difficulties in assessing the effectiveness of the AI intervention among patients. Subgroups, frequently impacted by restricted healthcare access and may be inadequately represented in clinical Experiments [28]

IX. CURRENT CONTROVERSIES

The recent, prominent debates surrounding research Ethical standards emerged with the release of a remarkably assertive article in the New England Journal of Medicine (Lurie & Wolfe, 1997). Public Citizen’s medical investigators Sidney Wolfe and Peter Lurie A reported incident they believed to be a shocking violation. Of ethical research standards in cooperative global AIDS clinical studies in developing nations. In 1994, representatives from the WHO, UNAIDS, and the US NIH and the US CDC developed placebo-controlled [29]

X. ETHICAL OVERSIGHT

Traditional ethical principles that regulate clinical trials include: respect for individuals and communities, beneficence, and Fairness. For the complete implementation of these principles, ethical supervision of clinical research studies is required. In favor of this perspective, international ethical research guidelines highlight the importance of oversight. Study by an ethics review committee (ERC). It additionally details the principles and behaviors that ought to be executed as a component of the ethical standards in human research. Following the instructions of the Office for Human Research Protections (OHRP) state that if the project possesses the scientific validity to produce knowledge, then data is gathered. Methodically to enhance patient care in the future and adds to the field, it is regarded as research and Needs ethical assessment. Criteria considered for participation in REC review include: the objective of the project, the Project design, funding source, data distribution. These criteria assist in assessing whether a project is an investigation and necessitates a REC summary. Research where the role of patients extends beyond mere care and instead, they are contributing to enhance patient care, the function of the ethical committee is vital to guarantee patient safety. Moral. A committee review is essential for all studies that include human subjects and for sponsors who plan the research. The project must not determine ethical approval because of potential conflicts of interest. [30]

XI. CONCLUSION

Ethical considerations in clinical trials are essential to ensure the protection, dignity, and rights of all participants. Upholding principles such as informed consent, fair participant selection, and careful risk-benefit analysis is critical for maintaining public trust and scientific credibility. Regulatory frameworks like the Declaration of Helsinki, the Belmont Report, and Good Clinical Practice (GCP) provide crucial guidelines to ensure ethical integrity. As clinical research continues to evolve, continuous ethical oversight, particularly through institutional review boards (IRBs), remains vital. Ultimately, ethical clinical trials not only protect participants but also strengthen the development of safe and effective medical therapies.

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

XII. ACKNOWLEDGEMENT

I, Ms. Shweta Navale, sincerely express my gratitude to the B. Pharmacy Department of Mahadev Kanchan College of Pharmaceutical Education & Research, Uruli Kanchan, Pune, Maharashtra, for their constant support and encouragement during the preparation of this review article. I am especially thankful to my respected faculty members and mentors for their invaluable guidance and insightful suggestions. Their support played a significant role in shaping this work. I also acknowledge the contributions of researchers and authors whose studies have served as key references for this review.

REFERENCES

[1] Venkataramana Kandi*, Sabitha VadakedathEthical Considerations in Clinical Research: A Comprehensive ReviewVenkataramana Kandi, and Sabitha Vadakedath, “Ethical Considerations in Clinical Research: A Comprehensive Review.” American Journal of Public Health Research, vol. 10, no. 2 (2022): 42-52. doi: 10.12691/ajphr-10-22.

[2] Henry Silverman1Ethical Issues during the Conduct of Clinical TrialsCorrespondence and requests for reprints should be addressed to Henry Silverman,M.D., M.A., University of Maryland School of Medicine, Department of Medicine,10 S. Pine Street, Suite 800, Baltimore, MD 21201. E-mail: hsilverm@medicine.umaryland.edu

[3] Vasantha MuthuswamPresident, FERCI,Forum for Ethics Review Committees in India, Regd. Society in MumbEthical issues in clinical researchPerspectives in Clinical Research | January-March 2013 | Vol 4 | Issue 1

[4] Mario Negri Institute for Pharmacological Research, Via G. La Masa 19, 20156 Milan, IEthics in clinical research0168-8278/$36.00 - 2009 European Association for the Study of the Liver. Published by Elsevier B.V. All rights reserved.doi:10.1016/j.jhep.2009.07.005

[5] David S. Shimml and Roy G. Spece2 I Departments of Radiation Oncology and Internal Medicine, University of Arizona College of Medicine, Tucson, Arizona, USA 2 University of Arizona College of Law, Tucson, Arizona, USADrugs 46 (4): 579·584, 1993 0012·6667/93/00 I 0·0579/$03.00/0 © Adis International Limited. All rights reserved. DRU1308Ethical Issues and Clinical Trials

[6] Hyoung Shin Lee Ethical issues in clinical research and publicationKosin Medical Journal 2022;37(4):278-282 pISSN: 2005-9531 • eISSN: 2586-7024 https://doi.org/10.7180/kmj.22.132

[7] Kosin Medical Journal 2022;37(4):278-282 pISSN: 2005-9531 • eISSN: 2586-7024 https://doi.org/10.7180/kmj.22.132What is the role of the research ethics committee?Paternalism, inducements, and harm in research ethics J Med Ethics 2005;31:419–423.

[8] S. B. Thorat*, S. K. Banarjee, D. D. Gaikwad, S. L. Jadhav, R. M. Thorat Vishal Institute of Pharmaceutical Education And Research, Ale, Pune-412411.CLINICAL TRIAL: A REVIEWVolume 1, Issue 2, March – April 2010; Article 019 ISSN 0976 – 044X International Journal of Pharmaceutical Sciences.

[9] Juntra Karbwang & Cristina TorresEthical Issues Related to Clinical Trials Outside the International Conference on Harmonization RegionsISSN: Med. Chem. (2011) 3(12), 1457–1460

[10] Young, M.J.; Bodien, Y.G.;Edlow, B.L. Ethical Considerations in Clinical Trials for Disorders o fConsciousness. Brain Sci. 2022, 12, 211. Brainsci12020211 Academic Editor: Sergio Bagnato

[11] Miller J, Millum J. Ethical considerations in international clinical trial site selection. BMJ Global Health 2022;7:e008012. doi:10.1136/bmjgh-2021-008012

[12] Cecilia Nardin The ethics of clinical trialsecancer 2014, 8:387 DOI: 10.3332/ecancer.2014.387 Copyright: © the authors; licensee ecancermedicalscience.

[13] Autumn Dawn Ediger,1,* Birgit Limbach2 and Dieter Dannhorn3FDA Requirements for Clinical Investigations of Medical Devices: A Review for European ManufacturersQual Assur J 2003; 7, 32–40.DOI: 10.1002/qaj.210

[14] Steven S Coughlin*Ethical issues in epidemiologic research and public health practicedoi:10.1186/1742-7622-3-16

[15] S.A. White □ J.M. Barnes □ L. Gelinas Ethical Challenges in Clinical Research During the COVID-19 PandemicMulti-Regional Clinical Trials Center of the Brigham and Women’s Hospital and Harvard, 14 Story Street, Cambridge,MA 02138, USA e-mail: bbierer@bwh.harvard.edu

[16] Dan Kabonge Kaye1,2*Navigating ethical challenges of conducting Randomized clinical trials on COVID-19Kaye Philosophy, Ethics, and Humanities in Medicine (2022) 17:2

[17] Kaye Philosophy, Ethics, and Humanities in Medicine (2022) 17:2Drug development and globalizing clinical trialsEthical variability:American Ethnologist n Volume 32 Number 2 May 2005

[18] American Ethnologist n Volume 32 Number 2 May 2005ETHICAL ISSUES IN THE DESIGN AND CONDUCT OF CLINICAL TRIALSIN DEVELOPING COUNTRIESSounding BoardETHICAL ISSUES IN THE DESIGNAND CONDUCT OF CLINICAL TRIALS IN DEVELOPING COUNTRIESN Engl J Med, Vol. 345, No. 2 · July 12, 2001· 139

[19] Joseph R. Fitchett □Ethical considerations of clinical trials in the developing worldTransactions of the Royal Society of Tropical Medicine and Hygiene (2009) 103, 756—760

[20] Divya Vohora Jamia Hamdard University, New Delhi, IndiaETHICAL CONSIDERATIONS IN CLINICAL RESEARCHPharmaceutical Medicine and Translational Clinical Research.© 2018 Elsevier Inc. All rights reserved.

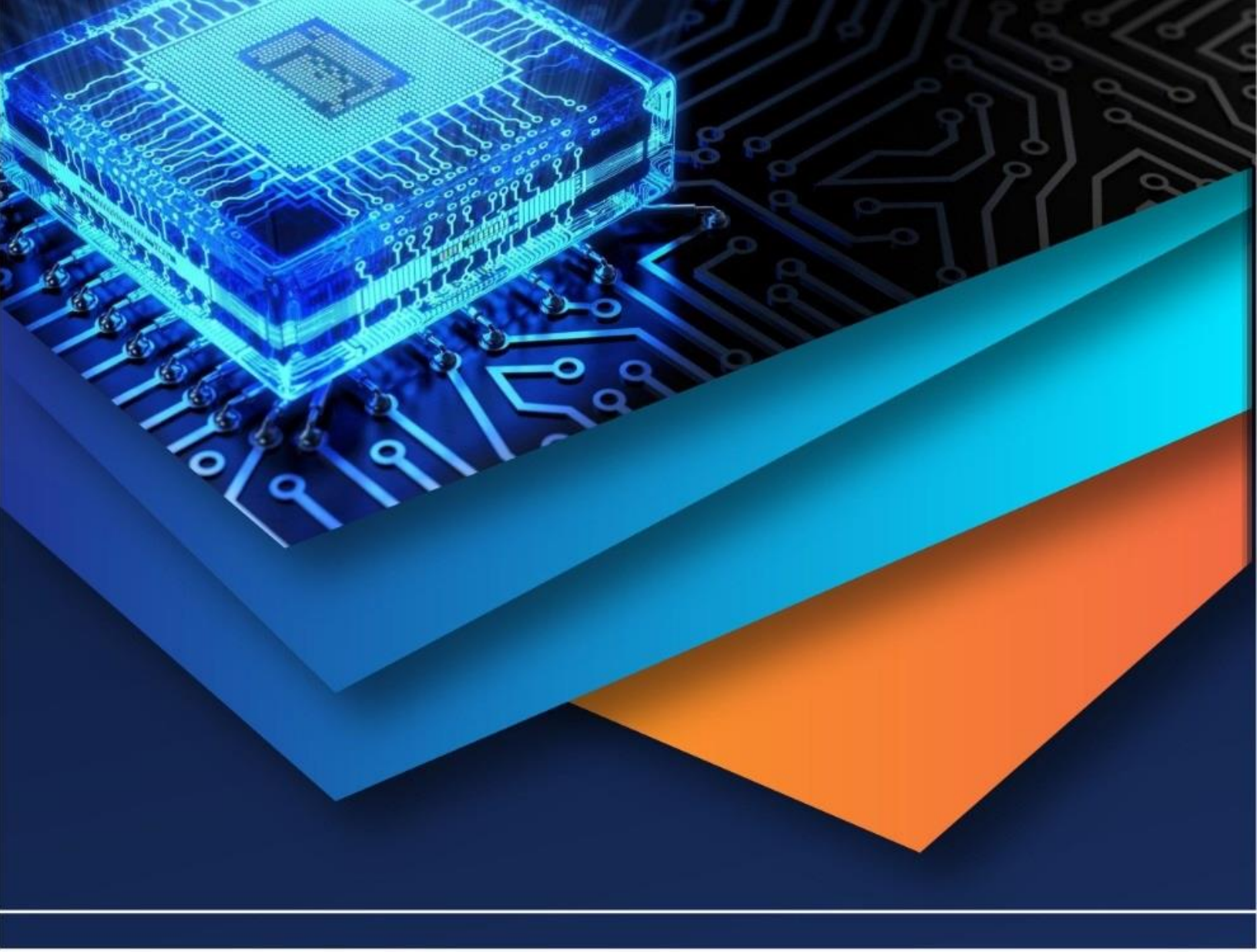
[21] S. M. MacLeod • D. C. Knoppert •M. Stanton-Jean • D. AvardPediatric Clinical Drug Trials in Low-Income Countries: Key Ethical IssuesPediatr Drugs (2015) 17:83–90 DOI 10.1007/s40272-014-0103-3

[22] Chairman: Robert J. Levine, M.D.Rapporteur: Dale H. Cowan, M.D.Ethical considerations in clinical trials Reprint requests to: Robert J. Levine, M.D., Professor of Medicine and Lecturer in Pharmacology, Yale University School of Medicine, 333 Cedar SI., Rm. C-407 SHM, New Haven, CT 06510Volume 25 Number 5 Part 2

[23] Wannes Van Hoof1 & Kevin Meesters2,3 & Lien Dossche4 & Daphné Christiaens4 & Pauline De Bruyne2 & Johan Vande Walle4Ethical considerations of researchers conducting pediatric clinical drug Trials: a qualitative survey in two Belgian university children’s hospitalsEuropean Journal of Pediatrics (2018) 177:1003–1008.

[24] Marija Bosnjak Pasic1,2, Branka Vidrih3, Helena Sarac2 , Hanna Pasic4, Luka Vujeviü4,Anamarija Soldo Koruga5 & Fabijan Rajiþ CLINICAL TRIALS IN DEVELOPING COUNTRIES - ETHICAL CONSIDERATIONSPsychiatria Danubina, 2018; Vol. 30, No. 3, pp 285-291.

[25] Jean-Claude K. Dupont, PhD, HOSPINNOMICS Chair, Paris School of Economics / AP-HPEthical issues of clinical trials in paediatric Oncology: A systematic review over 10 Year developments (2003-2013).© 2016 published by Elsevier. This manuscript is made available under the Elsevier user license.
[26] NUT KOONRUNGSESOMBOON, JUNJIRA LAOTHAVORN, and JUNTRA KARBWANGEthical considerations and challenges In first-in-human researchREV 5.4.0 DTD TRSL1053_proof 18 June 2016 1:33 pm ce
[27] CRAIG L. FRY Senior Research Fellow, Turning Point Alcohol and Drug Centre Inc., and Fellow, Department of Public Health, University of MelbourneTHE ETHICS OF PAYING DRUG USERS WHO PARTICIPATE IN RESEARCH: A REVIEW AND PRACTICAL RECOMMENDATIONS30, 2006
[28] Alaa Youssef, PhD; Ariadne A. Nichol, BA; Nicole Martinez-Martin, JD, PhD; David B. Larson, MD, MBA; Michael Abramoff, MD, PhD; Risa M. Wolf, MD; Danton Char, MD, MS Ethical Considerations in the Design and Conduct of Clinical Trials Of Artificial Intelligence JAMA Network Open. 2024;7(9):e2432482. Doi:10.1001/jamanetworkopen.2024.32482
[29] Udo SchuÈklenk University of the Witwatersrand, Faculty of Health Sciences, York Road, Parktown, Johannesburg 2193, South AfricaProtecting the vulnerable: testing times for clinical research ethicsU. SchuÈklenk / Social Science & Medicine 51 (2000) 969±977
[30] Maria Aziz1, Azma J. Khan2 and Sefia Khan3ETHICAL ISSUES IN CLINICAL TRIALS: A REVIEW OF THE RECENT LITERATURE, AN ETHICAL ARGUMENTATIONInt. J. Adv. Res. 9(01), 1079-1086



10.22214/IJRASET

45.98

IMPACT FACTOR: 7.129

IMPACT FACTOR: 7.429

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Call : 08813907089 (24*7 Support on Whatsapp)