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Transparency and Public Engagement in the M72/AS01E Tuberculosis Vaccine Trial in Indonesia: A Human Rights and Health Ethics Perspective

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Abstract:

The high burden of tuberculosis cases in Indonesia has prompted government involvement in phase three clinical trials of the new generation M72/AS01E vaccine. However, the implementation of this large-scale medical research on humans often neglects the right to information and the involvement of local communities around the research centers. This study aims to analyze the synchronization of national regulations and examine the implementation of the principle of public transparency and the dissemination of clinical trials of the M72/AS01E tuberculosis vaccine within the framework of human rights and international health ethics. The research method used is normative juridical supported by a socio-legal approach. Data were collected through a review of legal texts, scientific literature, and in-depth interviews with medical researchers, ethics committees, and civil society representatives in the area of Dr. Drs. M. Hatta Brain Hospital in Bukittinggi, one of the clinical trial locations. The results indicate a normative legal vacuum in which national regulations, particularly Law Number 17 of 2023 concerning Health and BPOM Regulation Number 8 of 2024, still focus solely on administrative product safety oversight. Domestic regulations do not explicitly mandate community engagement and disclosure of macro-level information beyond the direct research subjects. Empirically, outreach remains individual-centric through informed consent, fueling misunderstandings and the vulnerability of disinformation within the community. The study's conclusions confirm that clinical research accountability mechanisms in Indonesia are not fully aligned with international standards, including the Declaration of Helsinki and the 2016 CIOMS Guidelines. Implementing legal instruments mandating participatory risk communication is needed to ensure the protection of the right to information as a fundamental human right.

Keywords: clinical trials; health ethics; Human Rights; socialization; transparency.

INTRODUCTION

The provision of public health services and resilience is a direct manifestation of the mandate of Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia, which guarantees the right of every person to obtain health services. In order to realize optimal health standards, the state is obliged to undertake various disease control efforts, including through the development of health research and innovation. One of the public health

challenges that remains a serious concern in Indonesia is Tuberculosis (TB). Based on the Global Tuberculosis Report published by the World Health Organization (WHO), Indonesia ranks second in the world after India as the country with the highest burden of tuberculosis cases, with an estimated more than one million new cases each year. The high incidence of TB indicates that existing control strategies still need strengthening, including through the development of more effective vaccines (WHO, 2023). In this context, clinical research on TB vaccine candidates, such as M72/AS01E, is an important step in supporting disease prevention and control efforts. Clinical research not only contributes to the advancement of health science and technology, but also serves as a strategic instrument in realizing the right to public health. Therefore, the implementation of research must continue to uphold ethical principles, protection of participant rights, and legal certainty to ensure optimal benefits for society.

The limited effectiveness of the Bacillus Calmette-Guérin (BCG) vaccine, currently used in immunization programs, is a major challenge in tuberculosis control efforts. Although proven to provide adequate protection against severe forms of tuberculosis in children, the effectiveness of the BCG vaccine in adolescents and adults remains relatively limited. This situation is further exacerbated by the increasing number of drug-resistant tuberculosis cases, which pose a significant health, social, and economic burden, particularly in countries with high TB rates such as Indonesia. This situation has prompted the global health community to develop and test new vaccine candidates with higher efficacy in preventing infection and the progression of active tuberculosis disease. One candidate currently receiving widespread attention is the M72/AS01E vaccine. Based on previous clinical trial results, this vaccine has shown promising potential in providing protection against the development of tuberculosis in adults infected with Mycobacterium tuberculosis. Therefore, the development and further testing of the M72/AS01E vaccine is a strategic step in supporting the tuberculosis elimination target and strengthening the global public health resilience system (Gillard et al., 2016).

Indonesia's involvement as one of the countries hosting the Phase III clinical trial of the M72/AS01E tuberculosis vaccine represents a strategic step in supporting the development of global health innovations and accelerating tuberculosis control efforts. As a country with a high TB caseload, Indonesia's participation in this research has the potential to provide significant benefits, including access to cutting-edge health technology, strengthening national research capacity, and contributing to the discovery of a more effective vaccine. However, behind these benefits lie various legal, ethical, and human rights issues that require serious attention, given that this research involves human subjects on a large scale. Biomedical research is fundamentally oriented not only toward achieving scientific objectives but also must ensure the protection of the dignity, rights, safety, and well-being of research participants and the communities indirectly affected. In the context of the M72/AS01E vaccine clinical trial, one of the issues of concern is the transparency of information and the effectiveness of outreach by the research organizers to the public (Dye et al., 2013). Transparency is a fundamental principle in health research governance because it is closely related to the public's right to obtain correct, clear, and accessible information about research activities taking place in their environment.

Transparency in clinical trials cannot be limited to the administrative relationship between researchers, research sponsors, and regulators. Transparency should be understood more broadly as an obligation to provide adequate information to the public regarding the research objectives, implementation methods, potential benefits, potential risks, mechanisms for handling adverse events, and the form of accountability that will be provided in the event of harm to research participants. This type of information disclosure is crucial for building public trust and preventing misunderstandings, disinformation, and community resistance to health research programs. In practice, various challenges remain related to the implementation of the principle of information transparency in the implementation of clinical trials in Indonesia. The public often receives only limited information about ongoing research, while the space for public participation in the decision-making process is relatively minimal. This situation indicates a gap between the development of international standards regarding the protection of human rights in health research and the practice of regulating and implementing them at the national level. This is despite various international instruments emphasizing the importance of respecting the right to information, public participation, and the protection of vulnerable groups in all research activities involving humans (Pratt & Hyder, 2016).

Normatively, Indonesia already has a number of regulations governing the implementation of health research and clinical trials. The enactment of Law Number 17 of 2023 concerning Health and Regulation of the Food and Drug Monitoring Agency Number 8 of 2024 concerning Procedures for Approval of Clinical Trials demonstrate the government's efforts to strengthen the health research oversight and governance system. These regulations provide a legal basis for the licensing process, oversight, and protection of research subjects. However, the substance of existing regulations still tends to focus on the administrative and technical aspects of research implementation, such as fulfilling licensing requirements, product safety standards, and scientific

evaluation procedures. On the other hand, regulations regarding community involvement, widespread information dissemination, and the obligation to implement community engagement have not been regulated in detail and comprehensively. Yet, various international research ethics guidelines place community engagement as a crucial element in ensuring the accountability and social legitimacy of research. Community engagement serves not only as a means of conveying information but also as a mechanism for dialogue between researchers and the community to ensure that research is conducted with due regard for the needs, values, and interests of the local community (Tindana et al., 2007).

Previous studies on tuberculosis vaccine development in Indonesia have generally focused on the medical, epidemiological, and clinical effectiveness of vaccines. These studies have focused on measuring the safety, immune response, and effectiveness of vaccine candidates in preventing tuberculosis. Meanwhile, research examining the legal and human rights dimensions of clinical trial implementation is relatively limited. Existing legal studies largely focus on the validity of informed consent, or consent to research procedures, provided by individual participants after receiving an explanation from the researcher. However, the protection of rights in health research relates not only to the validity of informed consent but also to the public's right to information, the right to participate in processes that impact their community, and the right to protection from potential risks arising from research activities (MacQueen et al., 2015). Therefore, a more comprehensive approach is needed to assess the implementation of clinical trials, particularly with regard to information transparency and community involvement as part of human rights protection.

Based on these conditions, this study offers novelty through the use of an interdisciplinary perspective that integrates national health law, bioethical principles, and international human rights standards in analyzing the implementation of the M72/AS01E TB vaccine clinical trial in Indonesia. This approach is used to evaluate the extent to which the national legal framework is able to guarantee information transparency and public participation in the implementation of health research involving human subjects. Thus, this study is directed at answering two main questions. First, how is the harmonization of Indonesia's national legal regulations regarding information transparency and socialization in the implementation of vaccine clinical trials? Second, to what extent has the implementation of information transparency and socialization in the implementation of the M72/AS01E TB vaccine clinical trial in Indonesia fulfilled the public's right to information based on bioethical principles, international health standards, and applicable human rights instruments.

In analyzing the issues of transparency and publicity in the implementation of the M72/AS01E tuberculosis vaccine clinical trial, this study uses the legal protection theory proposed by Philipus M. Hadjon as a conceptual foundation. This theory positions legal protection as a crucial instrument to ensure the fulfillment of community rights and prevent actions that could harm citizens. According to Hadjon, legal protection consists of two forms: preventive legal protection and repressive legal protection. Preventive legal protection functions to prevent disputes by clearly regulating rights, obligations, and oversight mechanisms within a legal system. In the context of vaccine clinical trials, this form of protection is reflected in regulations governing information disclosure, informed consent, and the obligation of research organizers to provide accurate information to the public. Meanwhile, repressive legal protection plays a role in resolving disputes that have occurred, including through complaint mechanisms, law enforcement, and the provision of compensation if research participants or the public suffer losses due to the implementation of health research (Hadjon, 2017).

In the context of health research, preventive legal protection cannot be narrowly interpreted as merely ensuring the safety and quality of health products through regulatory oversight, such as the Food and Drug Monitoring Agency (BPOM). This protection must also encompass the fulfillment and respect of the non-physical rights of each research subject. These rights include the freedom to make voluntary choices without pressure, manipulation, or coercion, as well as the right to obtain complete, accurate, and understandable information before giving consent to participate in research. Thus, informed consent is not merely viewed as an administrative document, but as an instrument for protecting human rights and individual autonomy. Furthermore, this research also uses Human Rights Theory as a basis for analysis, particularly regarding the right to the highest attainable standard of health. This right is regulated in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) and clarified in General Comment No. 14. This instrument emphasizes that access to health information is an integral part of fulfilling the right to health, which must be respected, protected, and fulfilled by the state (Rid & Wendler, 2010). In these international legal instruments, the right to health cannot be separated from four key elements known as the AAAQ principles, namely Availability, Accessibility, Acceptability, and Quality.

The right to accessibility in the health sector is not only related to the availability of health services, but also includes access to relevant and accountable information. Within the framework of the right to health, the concept of

information accessibility emphasizes that every individual and community group has the right to seek, receive, and disseminate information regarding health conditions, public policies, and medical intervention programs implemented in their environment. This right must be guaranteed without disproportionate barriers, whether in the form of administrative restrictions, excessive bureaucracy, or the practice of withholding information by authorized institutions (Rid & Wendler, 2010). Information transparency is a crucial element in building public trust and encouraging community participation in health programs. To analyze the ethical aspects of conducting medical research, this study uses the Bioethics Theory developed by Tom L. Beauchamp and James F. Childress. This theory introduces four main ethical principles: respect for autonomy, beneficence, non-maleficence, and justice. These four principles serve as moral guidelines that must be applied in all stages of clinical trials to ensure the protection of the rights, safety, and welfare of research participants (Beauchamp & Childress, 2019).

The first principle in bioethics theory is autonomy, or respect for individual autonomy. This principle requires researchers to respect each person's ability to make free and rational decisions regarding their involvement in research. The principle of autonomy is implemented through the informed consent mechanism, which involves providing complete, honest, and understandable information regarding the research objectives, procedures, expected benefits, potential risks, and the participant's right to refuse or terminate participation at any time without adverse consequences (Toebes, 1999). Thus, the consent given by participants is not merely an administrative formality, but rather a form of respect for human freedom and dignity. The second principle is beneficence, or benefit. This principle emphasizes the researcher's moral obligation to strive for the greatest benefit for both research participants and the wider community. In health research, every research activity must be designed to generate knowledge or innovation that contributes to improving the quality of public health. Therefore, the benefits generated must outweigh any risks that may arise during the research process. The third principle is non-maleficence, which is the obligation to avoid causing harm or loss. This principle requires researchers to take various precautions to minimize the physical, psychological, social, and economic risks to research participants. Any potential negative impacts must be carefully identified, evaluated, and managed to ensure the safety and well-being of participants throughout the research (Spatz et al., 2016).

The principle of justice demands a balanced distribution of the benefits and burdens of research. No particular group of people should disproportionately bear the risks of research while others enjoy the benefits. This principle also requires equitable access to research results, especially for communities where research is conducted and who contribute as research participants. In the context of global health research, the application of these four bioethical principles becomes increasingly important because research often involves collaboration between international sponsors, research institutions, and local communities. Several studies have shown that the implementation of clinical trials in developing countries still faces challenges in the form of unequal power and information relations between transnational research sponsors and local communities. This imbalance can affect the quality of participant decision-making and raise doubts about the social legitimacy of research (Emanuel, 2000). Several studies in the field of international health law and bioethics also indicate that one of the weaknesses frequently encountered in the implementation of clinical trials in Southeast Asia is the limited transparency of public information and low community involvement from the research planning stage. In fact, information transparency and community engagement are crucial elements for building public trust, increasing the accountability of research providers, and ensuring that research implementation truly addresses the needs, values, and interests of affected communities (Pratt, 2019). Therefore, the application of bioethical principles needs to be understood not only in the relationship between individual researchers and research participants, but also in the broader relationship between research institutions and the communities in which the research is conducted.

In Indonesia, several previous studies have shown that relations in medical research are still dominated by paternalistic patterns, where medical institutions hold a much stronger position than the public, both as subjects and recipients of research impacts. This condition often limits public access to comprehensive information regarding the benefits, risks, and implications of biomedical research, resulting in public participation not fully based on adequate understanding. This finding indicates a gap between the principles of protecting research subjects stipulated in various international ethical standards and their implementation practices at the national level. Therefore, this study seeks to fill this research gap by critically examining the operational gap between Indonesian positive legal instruments and global ethical standards, particularly those contained in the 2016 CIOMS Guidelines, the Declaration of Helsinki, and the Good Clinical Practice (ICH-GCP) guidelines. The analysis focuses on the extent to which national regulations have accommodated obligations for transparency, disclosure of risk information, community involvement, and public disclosure of research results as part of protecting the rights of research participants and accountability in biomedical research implementation (CIOMS, 2016).

METHOD

This research was designed using a normative juridical research method combined with an empirical approach (socio-legal approach) (Irianto, 2021). The choice of a normative juridical design was based on the need to analyze the ambiguity of norms, the synchronization of laws and regulations, and the consistent application of legal principles related to clinical trials in Indonesia. Meanwhile, the socio-legal dimension serves as a bridge to observe, analyze, and evaluate how national positive legal texts operate, interact, and are implemented by actors in the field, in this case related to information transparency and outreach to the community surrounding the research center. The research targets or legal materials in this study are rigidly grouped into two main categories (Creswell, 2015). The first category is Primary Legal Materials which consist of binding national laws and regulations, including the 1945 Constitution of the Republic of Indonesia, Law Number 39 of 1999 concerning Human Rights, Law Number 11 of 2005 concerning Ratification of the ICESCR, Law Number 14 of 2008 concerning Public Information Disclosure, Law Number 17 of 2023 concerning Health, and BPOM Regulation Number 8 of 2024 concerning Procedures for Approval of the Implementation of Clinical Trials (Pai et al., 2016).

The second category is Secondary Legal Materials which contain international legal documents and supporting literature, including the Declaration of Helsinki, International Ethical Guidelines for Health-related Research Involving Humans (CIOMS 2016), ICH Guideline for Good Clinical Practice E6(R2), reputable legal journals, as well as global clinical trial registration data with registration number NCT06062238 onClinicalTrials.gov. Data collection techniques were carried out comprehensively through two main pillars: documentation studies and field interviews. Documentation studies were applied to conduct an inventory, classification, and critical review of all written legal materials (Sugiyono, 2023). To obtain a realistic portrait of legal implementation in the empirical setting, the author conducted structured in-depth interviews with key stakeholders. The interviews were conducted at the research location, namely the Dr. Drs. M. Hatta Brain Hospital in Bukittinggi, West Sumatra, which was chosen because it is one of the referral medical institutions and the center for the phase-three clinical trial of the M72/AS01E tuberculosis vaccine in Indonesia. Subjects interviewed included representatives of the health research ethics committee, the clinical trial research team, as well as community leaders and local residents living around the hospital area (Miles et al., 2014).

All collected data and legal materials were then processed using descriptive-qualitative analysis techniques. The first step was to conduct legal interpretation, specifically using systematic and grammatical interpretation methods to understand the philosophical and sociological meaning of each article in the Health Law and BPOM Regulations related to clinical trials. The second step was to apply normative-comparative analysis to map the existence or absence of legal gaps and inconsistencies between obligations stipulated in international standards and the reality of law enforcement in Indonesia. The narrative of the analysis results is presented descriptively to provide a complete, logical, and argumentative picture of the fulfillment of human rights in the vortex of global vaccine clinical trials (Sugiyono, 2019).

RESULTS AND DISCUSSION

Based on an investigation into the health legal subsystem following the enactment of Law Number 17 of 2023 concerning Health, it was found that the legal policy of codification of the health sector (Omnibus Law) in Indonesia places clinical trials as an integral part of national health research and development. Article 359 paragraph (1) of Law Number 17 of 2023 normatively emphasizes that any health research involving humans as research subjects must prioritize protection of life, health, privacy, and human dignity, and must obtain ethical clearance before the program is implemented. The technical details regarding the procedures for applying for clinical trials are then regulated in BPOM Regulation Number 8 of 2024 concerning Procedures for Approval of Clinical Trial Implementation (PPUK) (Tait et al., 2019). However, if this regulation is examined in depth using the theory of preventive legal protection, fundamental structural weaknesses are apparent. BPOM Regulation Number 8 of 2024 is dominated by technical-bureaucratic-laboratory regulations. The main focus of this regulation is to regulate the fulfillment of administrative files by sponsors or researchers, such as submission of product quality data, toxicity test results on experimental animals, compliance with clinical protocols, and proof of insurance policies for research subjects (Mashari, 2026).

Although BPOM Regulation Number 8 of 2024 regulates various technical aspects of clinical trial implementation, its substance still does not provide adequate attention to the dimension of public accountability, particularly regarding the fulfillment of the public's right to obtain information about ongoing health research. The regulation does not contain provisions explicitly requiring sponsors or research organizers to disclose research protocol summaries, provide information on research developments, or conduct open outreach to the public

outside the study participant group. The absence of these regulations creates a legal vacuum (rechtsvacuum) that has implications for limited public access to health research information (Zarzani, 2025).

This situation has the potential to create disharmony with Law Number 14 of 2008 concerning Public Information Disclosure. Article 4 of the Public Information Disclosure Law affirms that every citizen has the right to obtain public information, especially information related to the public interest and the well-being of the community, including health programs. However, in practice, various documents related to clinical trials are often categorized as exempt information for reasons of trade secret protection, intellectual property rights, or the confidentiality of research participants' medical data. Overly broad interpretations of the concept of confidentiality have the potential to hinder transparency and reduce the public's ability to monitor the implementation of health research that impacts the public interest (Mustofa, 2020).

A narrow and restrictive understanding of the concept of medical confidentiality has resulted in limited public access to various documents and information related to clinical trials in Indonesia. In practice, the principle of confidentiality is often overinterpreted, hindering the transparency of information necessary to ensure the accountability of biomedical research. This contrasts with practices in several countries that have developed integrated, transparent, and publicly accessible national clinical trial registration systems (Birkinshaw, 2010). Although Indonesia has a clinical research registration mechanism, a national registration center that functions optimally as a comprehensive, connected, and user-friendly source of public information is not yet available. As a result, civil society, patient organizations, academics, and the media struggle to obtain information about study design, clinical trial progress, and completed research results. Global research governance standards, however, place transparency in clinical trial registration as a crucial tool for strengthening public oversight, increasing researcher and sponsor accountability, and building public trust in health research and biomedical innovation (Kusnandar, 2025).

The phase three clinical trial of the M72/AS01E tuberculosis vaccine at Dr. Drs. M. Hatta Brain Hospital in Bukittinggi is part of a global research consortium involving thousands of subjects in several tuberculosis-endemic countries. The characteristics of the M72/AS01E vaccine, which uses a special adjuvant system to trigger a strong cellular immune response, require very strict monitoring and risk communication. Based on the results of the literature collection process, the fulfillment of individual medical subjects' rights has been carried out according to procedure. The researchers have read and submitted an informed consent form after explanation (informed consent), which contains information on the purpose of the injection, the schedule of regular visits, and potential local side effects such as pain at the injection site or fever. This indicates that the principle of autonomy at the micro-clinical level has been fulfilled. However, when this empirical reality is examined using the lens of international health ethics as outlined in the 2016 CIOMS Guidelines and the Declaration of Helsinki, a wide gap is found in the social dimension. Guideline Number 7 in the 2016 CIOMS Guidelines explicitly requires researchers, sponsors, and health authorities to implement proactive community engagement mechanisms (CIOMS, 2016).

The concept of community engagement in health research emphasizes the importance of active community involvement from the research planning stage. Prior to clinical trials, research organizers should establish communication and dialogue with various community elements, such as traditional leaders, community leaders, community organizations, and community groups near the research site. Through this process, the community has the opportunity to understand the research objectives, expected benefits, potential risks, and social and environmental impacts that could affect their lives. Furthermore, this mechanism also serves as a means to accommodate community aspirations, concerns, and perspectives regarding the research implementation. However, research results indicate that the practice of community engagement in the implementation of tuberculosis vaccine clinical trials in Bukittinggi has not been optimal. Based on various available literature and information sources, most residents living around the Dr. Drs. M. Hatta Brain Hospital were unaware of the ongoing global tuberculosis vaccine clinical trials. The community also reported never having received any official outreach or public education from the research organizers. This condition shows that research communication is still focused on individual research participants and has not yet reached the wider community as part of health research stakeholders (Hood, 2006).

Based on research findings, information about clinical trials is often disseminated in consultations between research physicians and prospective participants who meet the research criteria. This limited communication model indicates that the socialization process has not yet reached the wider community. As a result, information about the objectives, benefits, and risks of the research is only known to those directly involved, while the community surrounding the research site does not receive adequate access to this information. From a bioethical

perspective, this practice potentially violates the principle of justice, as the community, as part of the social environment impacted by the research, is not given an equal opportunity to understand the research activities taking place in their area. International health research ethics standards, however, place information transparency as a crucial element in protecting community rights. The CIOMS guidelines and the Declaration of Helsinki emphasize that transparency must be achieved through various mechanisms, such as publicly accessible research registries, community involvement in the research process, and open and continuous disclosure of risk information. Thus, transparency serves not only as an instrument of research accountability but also as a means of fulfilling the community's right to obtain true, accurate, and accountable health information (World Medical Association, 2013).

Regarding research registration, global ethical standards require that all clinical research be registered in an easily accessible public database before the first subject is recruited. This provision aims to ensure research accountability, prevent data manipulation, and provide public access to information regarding ongoing research developments. However, in Indonesian practice, research registration is generally only conducted on global platforms such as ClinicalTrials.gov, without a national transparency portal in Indonesian that is easily accessible to the public. This situation makes it difficult for the domestic public to legally and transparently obtain information about research developments, objectives, and results. Consequently, an information gap arises between research implementers and the public, who are directly impacted by health research (Sulianta, 2025).

In its principle of community engagement, the CIOMS guidelines emphasize the importance of active involvement of local communities in every stage of research to build public trust, increase informed participation, and minimize social conflict. However, in its implementation in Indonesia, community engagement is still viewed more as a moral imperative than a binding legal obligation. To date, there is no explicit regulation in Law Number 17 of 2023 concerning Health or technical regulations of the Food and Drug Monitoring Agency (BPOM) that mandates active community involvement in health research. This situation has implications for the emergence of hidden social resistance in society, low levels of public trust in health research, and increased public vulnerability to the spread of disinformation and hoaxes related to clinical trials. Furthermore, in terms of risk communication, international ethical standards require regular dissemination of information regarding the safety profile of research, adverse events following medical procedures, and potential risks that research subjects may experience. Risk transparency is part of respecting the public's right to obtain accurate and accountable health information (Purwoningsih, 2025).

In the practice of conducting health research in Indonesia, information regarding side effects, adverse events, and safety developments in research tends to circulate only within the internal environment of researchers, ethics committees, and supervisory authorities. Public access to this information is relatively limited because there is no transparency mechanism that allows the public to obtain information easily, quickly, and sustainably. This situation has the potential to undermine the public's right to access health information, which is a crucial component of protecting public rights in the health sector. Limited transparency can also impact public trust in the research process carried out by health institutions, academic institutions, and the government. When information about risks and research developments is not communicated openly, the public sphere becomes vulnerable to speculation, misinformation, and doubts about the credibility of research results. This situation demonstrates a gap between the principle of transparency developed in various international research ethics guidelines and the practice of regulating and implementing health research in Indonesia. This gap not only raises legal issues related to the protection of the right to information but also has broader social implications, such as declining public trust, weakening the legitimacy of health research, and reducing the effectiveness of health policies that depend on public support and participation (Darmadipura et al., 2013).

From a human rights perspective, limited public outreach regarding clinical trials demonstrates the failure to ensure information accessibility, an integral part of the right to the highest attainable standard of health, as recognized in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The right to health encompasses not only the availability of health services but also guarantees public access to accurate, transparent, and evidence-based health information. In this context, the state has an obligation to respect and fulfill the public's right to information related to health research activities that have the potential to impact the public interest. Lack of communication and outreach to the public can lead to various undesirable social consequences. The lack of clear information has the potential to trigger rumors, misunderstandings, and negative perceptions regarding the safety of health facilities and ongoing research activities. Furthermore, if serious adverse events occur later, the lack of adequate communication can increase the risk of social panic and undermine public trust in health institutions. This condition is exacerbated by the absence of provisions that

provide firm administrative sanctions for sponsors or researchers who ignore public information disclosure and community involvement, so that less participatory research practices still have the potential to continue in the health research system in Indonesia (Johan et al., 2026).

The regulation of clinical trials in the Indonesian health legal system following the enactment of Law Number 17 of 2023 concerning Health has provided a strong legal basis for the protection of research subjects. Article 359 paragraph (1) emphasizes that all research involving humans must prioritize the protection of life, health, privacy, and human dignity and must obtain ethical approval before conducting the research. This provision demonstrates that the state has adopted modern bioethical principles, particularly the principles of respect for individuals and the principle of non-maleficence in health research. However, the findings of this study indicate that existing protections still focus on the relationship between researchers and individual subjects. Furthermore, this approach has not yet evolved towards a broader, community-based protection model, in which communities surrounding the research also have the right to transparency of information, involvement in oversight, and protection from potential risks of research conducted in their area. This demonstrates the need for strengthened regulations and implementation that not only emphasize individual protection but also consider the social, ethical, and public responsibility dimensions in every clinical trial implementation in Indonesia to ensure fair, balanced, and sustainable protection oriented towards the interests of the wider community (Alfarizi & Listyaningrum, 2024).

These findings indicate a gap between national regulatory approaches and developments in international health research ethics. A systematic examination reveals that BPOM Regulation No. 8 of 2024 primarily regulates the administrative and technical aspects of clinical trial implementation, such as research protocol requirements, product safety documentation, preclinical testing results, researcher qualifications, and the mechanism for granting approval for clinical trials. These regulations are crucial for ensuring the scientific validity and safety of research. However, the regulation does not explicitly stipulate the obligations of sponsors and researchers to conduct public outreach, disclose research protocol summaries to the public, or establish community engagement mechanisms prior to research. Consequently, the available legal protection remains procedural and administrative in nature, but does not fully address the growing need for social protection in modern health research practices (Toebes, 1999).

From the perspective of preventive legal protection theory, this situation indicates that the state still places a premium on preventing individual risks to research participants. Regulatory focus is more directed at direct protection for clinical trial subjects, such as safety, the right to information, and informed consent. However, the social dimension of risk has not received equal protection. Yet, health research, particularly vaccine clinical trials, not only impacts the individuals directly involved as participants but can also have broader consequences within society. These impacts can include changes in public perception of medical interventions, the emergence of social concerns, the spread of inaccurate information or rumors, and even potential resistance to government-run health programs. In this context, a preventive approach should not only be oriented toward preventing individual harm but also encompass social risk mitigation through strengthening information transparency, public education, and effective risk communication mechanisms. Therefore, legal protection in clinical trials needs to be developed to be more comprehensive in order to address the challenges of both individual and social impacts in a proportional and sustainable manner (Tribowo, 2014).

Preventive legal protection should not only focus on the safety of research subjects but also encompass the public's right to obtain true, accurate, and easily accessible information regarding ongoing research. In this context, research findings demonstrate a normative tension between the medical confidentiality regime and the principle of public information disclosure. On the one hand, confidentiality is necessary to protect the personal data of research participants and the intellectual property rights of sponsors. However, on the other hand, the principle of transparency demands the disclosure of information so that the public can understand the risks, benefits, and objectives of clinical trials conducted in their environment. In practice, a number of documents related to clinical trials are often categorized as confidential information for this protection. Legally, this rationale has a valid basis within the data protection and intellectual property rights systems. However, if overapplied, it can reduce public participation and hinder the function of social oversight. Therefore, a proportional balance is needed between confidentiality protection and information disclosure so that the principle of preventive legal protection can be implemented effectively and fairly (Hatta, 2020). However, problems arise when the principle of confidentiality is applied too broadly, blocking public access to information that is not actually classified as confidential, such as research objectives, location, number of participants, research stages, protocol summaries,

and completed research results. As a result, the public loses the opportunity to exercise social oversight over research taking place in their communities.

In this context, Law Number 14 of 2008 concerning Public Information Disclosure essentially guarantees that every citizen has the right to obtain information relating to the public interest. This right reflects the principle of transparency in state administration, including in the health sector. Health research programs involving humans and having the potential to influence national health policy can be categorized as information containing significant public interest dimensions. Therefore, transparency of information regarding the implementation of clinical trials, research objectives, methodologies, and potential risks and benefits is crucial to ensuring the accountability of research implementation. However, the implementation of this principle of transparency often faces limitations related to personal data protection, research ethics, and the commercial interests of sponsors. This situation requires a proportional interpretation to avoid conflicts between the public's right to know and certain confidentiality obligations. Thus, the Public Information Disclosure Law can function as a preventive legal instrument that not only guarantees access to information but also encourages the creation of transparent and accountable health research governance that consistently prioritizes the protection of research subjects (Irianto, 2021).

A more proportionate approach is needed to balance the protection of trade secrets, the privacy of research participants, and the public's right to information. Information containing personal data or scientific formulas can remain protected, while information relating to the research objectives, benefits, general risks, and progress of the research should be publicly accessible (Faden & Beauchamp, 1986). The lack of transparency is further evident in the suboptimal national clinical trial registration system. Currently, most clinical research conducted in Indonesia is registered on international platforms such as ClinicalTrials.gov or registries recognized by the World Health Organization. However, these platforms have not been able to meet the needs of the Indonesian public due to language barriers, limited health literacy, and low levels of public awareness of the registry. As a result, information about research conducted in Indonesia is more easily accessible to the international scientific community than to the Indonesian public.

This situation demonstrates a gap between the concepts of formal transparency and substantive transparency. Formally, the research has been registered in accordance with international regulations. However, substantively, the affected communities have not yet received adequate access to this information. Therefore, it is necessary to develop an integrated national registration system that uses Indonesian, is easily accessible to the public, and provides information that is understandable to the general public. Such a system serves not only as a means of research administration but also as an instrument of public accountability and strengthens public trust in health research (Soekanto, 2018). The case of the implementation of the phase III clinical trial of the M72/AS01E tuberculosis vaccine at the Dr. Drs. M. Hatta Brain Hospital in Bukittinggi concretely demonstrates how this gap occurs in practice. Based on the research results, the rights of individual research subjects were fulfilled through an informed consent mechanism. Research participants received an explanation of the research objectives, visit schedule, expected benefits, and possible side effects. Thus, the principle of autonomy at the individual level can be said to have been implemented in accordance with applicable ethical standards (Asshiddiqie, 2008). However, when analyzed using the 2016 CIOMS Guidelines and the Declaration of Helsinki, fulfilling informed consent cannot be considered sufficient to fulfill all ethical obligations of research providers. Modern research ethics has evolved from an individual paradigm to a social paradigm that places the community as a vital part of the research process. Therefore, the concept of community engagement is a key component that must be fulfilled. Community engagement is not simply a formal outreach activity, but rather a two-way dialogue process that allows the community to understand the research objectives and express their aspirations and concerns.

The research results indicate that community involvement in the implementation of the clinical trial was not optimal. Outreach was only provided to individuals who met the criteria for research participants, while the community living near the research site did not receive adequate information about the ongoing activities. This situation indicates that the research was still conducted with an approach oriented toward the doctor-patient relationship and had not adopted the participatory approach characteristic of contemporary research ethics. From a bioethical perspective, this situation has the potential to raise justice issues. The community surrounding the research site shares various social consequences of the research, such as changes in perceptions of health facilities, the emergence of vaccine safety issues, or other potential social impacts. However, they did not have an equal opportunity to understand the objectives and risks of the research. In other words, the distribution of information was not fair, placing the community at a disadvantage compared to the research institution (Nasution, 2017).

Lack of community involvement can impact public trust in health research. Various international studies have shown that public trust is a crucial factor in determining the success of clinical research and public health programs. When information is not readily available, the public sphere tends to be filled with speculation, rumors, and disinformation. This phenomenon is particularly relevant in the Indonesian context, which has faced challenges in recent years, including the spread of health hoaxes through social media. The lack of transparent communication can actually reinforce negative narratives and undermine the legitimacy of research that actually offers significant benefits to public health. The findings of this study can also be analyzed from a human rights perspective, particularly the right to health, as stipulated in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The right to health encompasses not only the availability of health services but also access to accurate and accountable health information. Within this framework, information about health research is part of the public's right to knowledge related to health conditions and public health policies (Banakar & Travers, 2005). Therefore, the lack of transparency in clinical trials can be seen as a form of suboptimal fulfillment of the right to health information.

The root of the problem identified in this study lies in the absence of legal norms explicitly mandating public information disclosure and community involvement in health research. Current national regulations still position these aspects as voluntary practices or merely ethical recommendations, rather than as legal obligations accompanied by firm oversight mechanisms and clear sanctions. As a result, the implementation of transparency principles in clinical trials is highly dependent on the commitment of individual sponsors or researchers, resulting in inconsistent and varied practices in the field. In many cases, information disclosure is only implemented to the extent that it does not conflict with the interests of sponsors or the internal regulations of research institutions. This situation differs from regulatory developments in several other countries, which have integrated the obligation to publicly register research, publish research results, and involve communities as part of a binding legal system. This difference indicates a normative gap that needs to be addressed immediately by strengthening national regulations so that the principles of transparency, accountability, and public participation in health research can be ensured more effectively and sustainably (Koeswadji, 1998).

Based on these findings, it can be concluded that the main problem with health research in Indonesia lies not in the lack of regulation, but rather in the regulatory orientation, which still focuses on individual protection and administrative compliance. Meanwhile, developments in international research ethics have moved toward a paradigm of transparency, public participation, and social accountability. Therefore, future health law reforms need to be directed at strengthening community engagement obligations, developing an open national clinical trial registry, mandating the publication of research summary results, and establishing sanctions for research providers who ignore the public's right to health information. These steps are crucial for realizing health research governance that is not only legally valid, but also socially and ethically legitimate.

CONCLUSION

Based on the research and analysis conducted, it can be concluded that Indonesia's national legal framework regarding transparency and public awareness of clinical trials is not fully aligned with the development of global health research ethics standards and international human rights principles. Although Law Number 17 of 2023 concerning Health and BPOM Regulation Number 8 of 2024 have provided a legal basis for the implementation of safe and ethical clinical trials, the regulations are still oriented towards administrative, technical, and individual protection aspects of research subjects. These regulations do not explicitly stipulate the obligation to disclose public information, communicate health risks, or involve the community as an integral part of accountable health research governance. Empirical findings from the implementation of the M72/AS01E tuberculosis vaccine clinical trial at Dr. Drs. M. Hatta Brain Hospital in Bukittinggi show that the principle of informed consent has been applied to research participants in accordance with applicable ethical provisions. However, public awareness and information dissemination are still limited to individuals who are research subjects, while the community around the research site does not have access to adequate information regarding the objectives, benefits, and potential risks of ongoing research. This situation indicates a gap between research practices in Indonesia and international standards, particularly the 2016 CIOMS Guidelines and the Declaration of Helsinki, which emphasize the importance of community engagement, transparency, and risk communication as instruments for protecting public rights. Therefore, strengthening legal policies is necessary through the creation of derivative regulations that explicitly mandate community engagement, public risk communication, and transparency of health research information. Furthermore, the government, through the Ministry of Health and the

Food and Drug Authority (BPOM), needs to develop a national clinical trial registration system that is integrated, transparent, easily accessible, and uses language that the public can understand. This step is crucial for strengthening research accountability, increasing public trust, preventing health disinformation, and ensuring the fulfillment of the public's right to health information as part of human rights protection.

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