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◀ EDITOR ▶

Dr. Vinay Shankarrao Hatole

Assistant Professor, International Center of Excellence in Engineering
& Management (ICEEM) College, Waluj, Chhatrapati Sambhajanagar. (MS)

◀ PUBLISHED BY ▶



AJANTA PRAKASHAN

Jaisingpura, Chhatrapati Sambhajanagar. (MS)

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5. Medical Experimental Health Record Confidentiality in Clinical Trials

Mr. Kalichand Govardhan

Research Scholar

Dr. Pratima R. Lokhande

Associate Professor & Research Supervisor, Dr. Ambedkar College, Department of Law,
DeekshaBhoomi, Nagpur.

Abstract

The protection of sensitive subject data has become a primary concern as digital tools such as health records are being incorporated into the clinical research environment in India. In clinical trials subjects private health data that needs to be protected from abuse and illegal access in order to preserve patient confidence and clinical trial integrity. Informed permission and respect for participant privacy are prerequisites for ethical clinical research. This procedure guarantees that before consenting to participate, participants are well informed of the trial's goals, risks, and advantages, free from coercion.

The Indian Council of Medical Research emphasizes the need of open, voluntary participation in clinical trials and offers national guidelines for informed consent. However, there is an increasing need to bring India's data protection policies into compliance with foreign norms, such the General Data Protection Regulation as digital health records become more prevalent. This study explores how India may improve its regulatory framework to preserve patient privacy and conform to international data security standards by analyzing the ethical and legal issues surrounding informed consent and data protection in clinical research.

Key words: Informed Consent, Clinical Trials, Confidentiality, Ethical and Legal Requirement, Medical Treatment.

Introduction

Protecting a person's privacy in clinical research with human subjects is a core ethical obligation that goes far beyond simply fulfilling legal requirements. According to both national and international research norms, protecting medical and personal data is crucial to preserving the integrity of the study process. The potential of privacy violations, unauthorized data disclosure, and improper treatment of sensitive information has increased with the adoption of

digital systems such as health records in healthcare and research settings. As a result, these issues require careful, continuous attention.

The notion of informed consent is fundamental to research that adheres to ethical standards. This idea is far more than just getting a participant to sign a document; it's a continuous, open dialogue between the participant and the research team. Through this approach, participants receive comprehensive and intelligible information about the study, including its goals, methods, possible risks, and advantages. More significantly, it upholds each participant's freedom to freely and voluntarily decide whether or not to participate without feeling coerced or misinformed. By doing this, it protects each participant's autonomy and dignity when they decide to participate in a study.

Experimental medications, cells and other biological products, surgical and radiological procedures, medical gadgets, health maintenance, behavioral treatments, and care processes are only a few examples of clinical trial interventions.

Clinical trials are defined by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and Good Clinical Practice (ICH GCP) as any study conducted on human subjects with the goal of determining the safety and/or efficacy of an investigational product or products, as well as any adverse reactions to the product or products, as well as the absorption, distribution, metabolism, and excretion of the product or products.

There was a study published in an Indian medical journal, and they referred to several medical experimental cases, like the Nazi medical experimental case, the Belmont report, the Nuremberg Code, the ICMR guideline, the India GCP guideline, and the ICM GCP guideline. After the study, all summaries of certain universal ethical requirements for that we have seven ethical principles to regulate clinical trials, which should have value to the society.

1. Scientific value and validity.
2. Social value.
3. Fair subjects or volunteer selection.
4. Favorable benefits and risk ratio.
5. Independent review and accountability.
6. Informed consent and subject rights.

In clinical trials ethical committee and the National Council for Human Resources in Health agencies prescribing standards to conducted the clinical trials to find out new drugs and techniquines with proper planning and coordinated development of medical and allied health education throughout the country. (Ethical Guidelines for Biomedical Research on Human Participants, 2023)

Statement of the Problem

1. To protecting the interests of the subject without endanger the delicate Doctor- patient relationship between them pertaining to the legal aspect.
2. The Judicial decision for the protection of subject's rights and the accountability of the Doctors under the law of negligence has emerged as a debatable issue among the medical fraternity.

Significance of Study

1. The clinical trial is significant protect the value of human life which cannot be left carefree in the hands of negligent clinical trials researcher who diverted their duties from the professional code of ethics.
2. A subject who have hopefully surrenders himself in clinical trials with full faith to his doctors.
3. The medical practitioners, who owe immense onus to provide Medicare to the society, are under obligation to discharge their duties with care, skill and assiduity.

Objectives of study

1. Informed consent plays a crucial role in ensuring subject confidentiality and data protection during research
2. To empower participants to make informed decisions about their involvement, respecting their autonomy and promoting ethical research practices.
3. To providing clear and comprehensive information about the study, including potential risks and benefits.
4. To ensuring participants understand the purpose and procedures of data collection.

Sources of Data Collection

1. The relevant material can be collected from primary as well as secondary Sources.
2. Material and information can be collected from various national enactments, legal and other sources like published works, Law Journals and websites on various topics.

The book's editors collected papers about many facets of the right to health. Through a detailed description of human rights and its viewpoint on health, the book primarily focuses on the relationship between health and human rights. Establishing development as a fundamental human right and establishing it as a human right to health is done through established treaties. Subsequently, it links human rights and health to development and developing technology. It also outlines the obligations of states and non-state actors to provide, uphold, and fulfill everyone's right to health. It talks about the part medical professional's play in preserving and advancing health. Since no right can exist in isolation and the right to health can be better promoted when human rights are also upheld, the book focuses on how rights relate to one another.

History of Human Experimentation

Experiments on human subjects are not a recent development. Historians have shown that the practice of examining guilty persons was common in ancient Alexandria but disappeared between the time of Rome and the Middle Ages. However, even in medieval times, erroneous instances of human experimentation were discovered in certain civilizations. The purpose of these experiments was to examine the changes that occur in the human body immediately before and after execution.

The number of human experiments in the 19th and 20th centuries has increased once more. However, those individuals were utilized for vulnerable human experimentation until the middle of the 20th century. history of using condemned and executed people in experiments. Therefore, the idea of consent was not even regarded as standad practice in human experiments. These experiments' subjects were not treated like human beings, and the settings under which they were carried out on living people were extremely dehumanizing. These tests were conducted in the past to observe how weaponry affected the body, and later to purge the body of impurities and purify the race. Last but not least, the development of novel diagnostic methods and medications for the benefit of humanity and the progress of medical knowledge is the current justification for human clinical trials.

After years of conflict between the axis and allied countries, the allied powers won World War II in 1945. The winning nations established an International Military Tribunal to try the top military and political criminals as well as other war criminals. The first trial, which is renowned as the "Doctor's Trial," began in 1947 in Nuremberg, Germany, which was then occupied by the US military. It was started against 23 German doctors.

Role of informed consent in clinical trials

In clinical trials, the subject must give informed consent, which is viewed as the same as getting the subject's signature on the consent form. Informed consent can be obtained in a research subject's verbal or written form. Informed consent is only part of the process. Informed consent involves a potential subject with Sufficient information to provide subjects those who are involving clinical trials.

- a. Recognition and facilitation of the potential subject's understanding of the information about clinical trials.
- b. The subject should get appropriate time to ask questions and to discuss with family and friends about the clinical trials.
- c. The research subject must have obtained the potential to ask the question about the clinical trials.
- d. The clinical trials center must provide continuing information as the clinical investigation progresses to the subject and their relatives.

When some new medicine, cosmetics, or food stuff is to be marketed, its suitability has to be confirmed by applying the invented medicine, cosmetics, or food stuff to human subjects. It becomes necessary that certain types of medicine cannot be experimented on human subjects directly. Such experiments are conducted on animals first, results are analyzed, and if found satisfactory, they are applied to human subjects next.

Subjects who participate in scientific research are generally of two categories. The first category is healthy volunteers, and the second category is patients. In each category there shall be persons of different age groups, viz., infants, children, adults, and elderly persons. Healthy volunteers are recruited through advertisements in the media. Apart from recruited volunteers, medical, nursing, and pharmacy institutional students and interns also participate in research studies. These calls from volunteers are the most wanted ones.

Subject enrolling in a clinical trial:

Every participant must be adequately informed about the nature and structure of the clinical trial before enrollment. The process of informed consent must include detailed disclosures and ensure that the individual fully understands all aspects of the trial.

Key elements to be disclosed include

Statement of Research Purpose: A clear declaration that the study is research-based, including a description of how it contributes to medical knowledge or treatment development.

Explanation of Research Goals: The objectives of the trial should be articulated, such as evaluating drug efficacy, discovering side effects, or comparing treatment approaches.

Duration of Participation: Participants must be informed of how long they will be involved in the study, including the frequency of visits, follow-ups, and total time commitment.

Procedural Description: All procedures standard and experimental must be described in detail, including medical tests, blood draws, imaging, or surveys.

Explanation of Experimental Interventions: If any aspect of the treatment or drug is investigational, this must be clearly stated, along with potential unknown risks.

Disclosure of Risks and Benefits: The possible side effects, discomforts, or inconveniences should be listed alongside the anticipated benefits, even if minimal.

Right to Withdraw: Participants must be told explicitly that they can withdraw at any time without penalty or loss of benefits.

This process ensures transparency and promotes autonomy, empowering participants to make decisions based on full knowledge of what the trial entails.

Confidentiality of clinical trials information:

Clinical trials involve collecting a large volume of personal data from participants. Protecting this information is essential, especially as digital health records and trial databases are increasingly used for data storage and analysis.

- Personal data collected during a clinical trial may include: (e.g., name, age, gender, address).
- Medical history and diagnosis.
- Test results, scans, and laboratory findings.
- Treatment protocols and outcomes.

This information is typically stored in secure databases, where each participant is assigned a unique identification code or number. Instead of using names, researchers refer to participants by their assigned ID to maintain anonymity. (Renu sobti, 2000)

To protect confidentiality

Access to data is restricted to authorized personnel only.

- Trial forms are encrypted and stored with password protection.
- Regular audits and security checks are conducted to prevent data breaches.

Participants are informed about how their data will be stored, used, and potentially published in anonymous form.

Breaches of confidentiality can severely damage the trust participants place in researchers and may also lead to legal consequences under data protection laws and ethical guidelines. Ensuring strong privacy standards is crucial throughout every stage of the research process.

Conclusion

It is completely voluntary to participate in clinical trials. People are free to decline participation or to leave at any time without fear of repercussions or prejudice. Participation must be chosen after careful consideration and personal judgment. Informed consent is a fundamental ethical obligation as well as a legal one. It ensures that during the trial, the participant's autonomy, dignity, and right to self-determination will be upheld. But in India, there is frequently a disconnect between the laws that are in place and how they are actually implemented. Participants may have minimal literacy, come from a variety of socioeconomic backgrounds, and have limited access to trustworthy medical information. This may make it more difficult for them to understand and provide informed consent. Adequate knowledge and risks associated with such trials information must be provided to the person. The experimentation must be carried out as per the rules, regulations and guideline as enumerated by the appropriate authority. The responsible person, the immediate family members must be informed about the risk associated and repercussions if attached to it.

Subjects are required to make a valid decision, and hence the process of informed consent demands that the patient should have adequate knowledge about it. It is seen that patients come from varied social and cultural backgrounds, with limited literacy about the process. Hence, it is suggested that innovative communication strategies should be developed to encourage and facilitate informed decision-making in India.

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