Page 320 - 343 **DOI:** *https://doij.org/10.10000/IJLMH.116124*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 6 | Issue 6

2023

Informed Consent for Clinical Drug Trials: Introspection to the Human Right Issues

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ABSTRACT

To regulate the doctor-patient relationship, the doctrine of informed consent has been established as a legal principle. This requirement consists of two distinct, but related legal obligations imposed on physicians: the first is to provide patients with information, and the second is to obtain their consent before administering treatment. Most doctors are hesitant to tell their patients about their disease, the treatment they are receiving to cure it, as well as the treatment's consequences and side effects. To compel physicians to inform patients about their illnesses, a strong legal framework is required. The doctrine of informed consent does not have the same application in the case of human trial and treatment. In treatment, a doctor extends the patient's knowledge about a known medicine and cure. But in the case of human trials, even the doctor cannot predict the results of such medication. If we analyse the international legal regime that regulates human experimentation, the entire process is regulated by this doctrine. From the Nuremberg Code to the Helsinki Declaration, informed consent is the unique standard upon which the trial is legalized. The doctrine of informed consent does have many limitations in regulating experimentations on human beings even though it is considered as a good tool to overcome the problem of medical negligence. Human rights issues in clinical drug trials are examined in this article.

Keywords: *Human Rights; Informed consent; Clinical drug trial; Medical jurisprudence.*

I. INTRODUCTION

The doctrine of Informed Consent[2] is the cornerstone of present-day medical jurisprudence".[3] It is important to note that, unlike treatment which also requires IC, in most of the clinical drug trials, the interest of the trial subject and the researcher may conflict.[4] There is a widespread consensus in International ethical codes and human rights instruments that medical researchers must obtain the free and informed consent of research participant in advance. It has become relevant after the "war crimes trials at Nuremberg which has shocked the world's medical community with the revelations about the experiments carried out by physicians in the death

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[2] Hereinafter referred as IC.
[3] Edward P. Richards & Katharine C. Rathbun, (1999). *Medical care Law.* New York: An Aspen Publication, p.205.
[4] Jonathan Montgomery, (1997). *Health Care Law*. London: Oxford University Press, p.346.

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camps. These experiments moved the discussion of consent for medical care from the philosophical to the practical. Any Individual who is of adulthood and sound mind has a right to determine that what activities should be done with his own body.[5] Investigators should not be permitted to intrude into an individual's privacy without their informed consent since privacy and confidentiality are considered to be the norms that are closely related to informed consent and minimization of risk.

The purpose of this paper is to provide an overview of the international and national legislative provisions governing informed consent and to evaluate how far this right had been ensured to trial subjects during CT.

(A) Meaning of Informed Consent

"The term Informed Consent means informing the potential enrollee about the objective and nature of the research, the details of the procedures for the study, the possible effect of the vaccine undertaken and its risks.[6] Informed consent will be needed for any invasive research.[7]

The concept of IC is internationally recognized and is available to all adult persons with normal mental faculties. "An intervention in the medical field can only be given after that particular individual has given the consent by informing and freely. The person undertaking the experiment shall prior to the experiment be given appropriate information regarding the purpose and nature of the intervention as well as its consequences and risks. The person who has given the consent may freely withdraw his or her consent.[8]Absence of inducement is considered as another factor for the consent to be free."

Article 2(j) of the Clinical Trials Directive defines Informed Consent as follows:

"*A decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation*."

[5] Nuremberg code 6, Helsinki part B. Common federal regulations United States.
[6] Lily Srivastava, (2ndedn.,2013). Law and Medicine. New Delhi: Universal Law publishing co. pvt. Ltd, p.224.
7 *Id.* at 334.
8 Supra 6.

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II. INTERNATIONAL PERSPECTIVE

(A) Nuremberg Code, 1947

The prerequisites of voluntary consent laid down in this code are legal capacity or competence to give consent. The trial subject should be informed about nature, duration, purpose, method; all the troubles and reasonable hazards are to be expected along with the effects on his personal health which may result from his participation.[9] The individual who initiates, direct or engages in the experiment has a duty and responsibility to ascertain the quality of the consent.[10]"During the experiment, if an individual has reached the physical or mental state where continuation of the experiment seems to him to be impossible, then he should have the liberty to end the experiment.[11]The code mandates that it is the duty and responsibility of each individual who initiates, directs, or engages in the experiment to ascertain the quality of the consent. This duty cannot be delegated to others with impunity as it is a personal duty and responsibility of that physician. The adequacy of the subject's consent required by the Nuremberg Code is in vague because the truly informed consent of the subject cannot be achieved due to the fact that the solution of the experiments is not known beforehand.

(B) Helsinki Declaration 1964

The rule of consent has been presented in all the versions of the Helsinki Declaration. The most prominent type of biomedical research involving Paragraph 22 to 26 of the declaration addresses the issue of consent.[12]The participation in the trial is only based on voluntary consent.[13] The privacy of the research subjects and the confidentiality of their personal information must be minimized to the impact of their physical, mental and social integrity by taking every possible precaution[14]. The collection, analysis, storage or reuse of the identifiable human material or data for the purpose of medical research must be done by the physicians only after obtaining the consent from that particular individual. Sometimes, a situation may arise where obtaining the consent will be impractical or impossible for the purpose of any such research. This hinderance can be removed only when the consideration and approval of a research ethics committee has been obtained.[15] If the potential research subject is incompetent for experimentation, then the

9 P. Weindling, (2004). Nazi Medicine and the Nuremberg Trials: From Medical War crimes to Informed Consent. Springer, p.7.
10 Nuremberg Code, 1947, Para.1.
11 *Id*. Para.9.
12 WMA Declaration of HELSINKI – Ethical Principles for Medical Research Involving Human Subjects, Available from:< https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [Accessed: 05 February 2021].
13 Helsinki Declaration 1964, Principle 22.
14 *Id*. Principle 23.
15 *Id.* Principle 27.

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physician has to necessarily obtain the consent of the legally authorized representative of that particular subject. The legally authorized representative cannot be part of the research study unless it is necessary for knowing the population representing the potential subject or in the case when the research cannot be performed without a competent person. Such research must have minimal risks and burden.[16]

Paragraph 30 addresses the ethical obligations of authors and publishers in reporting such work (and observes that any negative as well as positive results should be published or made publicly available)

"For obtaining and documenting the informed consent, the person who investigates should comply with the applicable regulatory requirements and he or she should adhere to GCP and the ethical principles provided in the Declaration of Helsinki. Before beginning the trial, the investigator should be having the IRB and IEC's written approval along with any favourable opinion of the written informed consent form. Any other written information must also be produced to them as well as the subjects.

(C) European Council Directive 2001

"The European Council Directive 2001 mandates that special protection must be given for the persons who are incapable of giving legal consent to clinical trials.[17] If the person has been suffering from dementia, psychiatric patients etc., then the clinical trials has to be conducted based on severe restrictiveness.[18] Moreover, the written consent from the patient's legal representative which was given by the representative with the cooperation of doctor has to be necessarily obtained in any of the clinical trial.[19] The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, authority and/ or a body provided by national law[20]."

III. NATIONAL PERSPECTIVE

(A) Schedule Y of Drugs and Cosmetics Rules, 1945

According to the Schedule Y of Drugs and Cosmetics Rules 145, each study subject must be accompanied with freely given informed consent. It is the duty of the investigator to provide the details of the study by using an information sheet of the patient verbally to him in a non-

[16] *Id.* Principle 29.
[17] Para 3 of the European Council Directive 2001.
[18] *Id*. Para. 4.
[19] Directive 2001/20/EC of the European Parliament and of the Council European Union of 4 April 2001, Available from: < http://www.eortc.be/services/doc/clinical-eu-directive-04-april-01.pdf>. [Accessed: 10 February 2021].
[20] *Id*. Para. 5.

technical way and it should be in a manner understandable by the subject.[21] The consent of the subject can only be obtained in writing by using an informed consent form.

(B) Ethical Guidelines for Biomedical Research on Human Participants or Indian Medical Research Code, 2006

Principles of Voluntariness, Informed Consent and Community Agreement[22]

It provides that research participants are fully apprised of the research and therefore the impact and risk of such research on the subject and others; and whereby the research participants retain the proper right to abstain from further participation within the research, regardless of any legal or other obligation which will are entered into by such human participants or someone on their behalf. Where any such research entails treating any community or group of persons as a research participant, those principles of voluntariness and consent shall apply, mutatis mutandis, to the community as an entire and to every member who is a part of the research and the experiment.[23]

The principle of voluntariness and informed consent shall duly be applied and any such consent and voluntariness in the case of a human participant becoming incapable of giving consent must be obtained through a person who has been empowered and has a duty to act on behalf of such a participant. The doctrine of informed consent and voluntariness are the core principles that an investigator or the person carrying on the experimentation must adhere throughout the research and experiment. The research participants in such experiments have a right to be continuously informed about the aftermath effect and all developments that had been occurred during the process along with its usage.

However, without in any manner undermining the cardinal significance of acquiring knowledgeable consent from any human player concerned in any research, nature and shape of the consent and the evidentiary necessities to show that such consent turned into taken, shall rely upon the diploma and seriousness of the invasiveness into the worried human contributors' man or woman and privacy, fitness and existence generally, and, the general reason and the significance of the research. Ethics committee shall determine at the shape of consent to be taken or its waiver primarily based totally at the diploma of threat that can be concerned.[24]

[21] Rule 4 of the Schedule Y of Drugs and Cosmetics Rules, 1945.
[22]Hereinafter referred as ICMR
[23] ICMR Code, 2006 Available from: www.icmr.nic.in [Accessed: 24 February 2021].
[24]*Id*. Principle II

(C) Principles of Accountability and Transparency

The study or trials should be done in a fair, honest, impartial, and transparent manner after individuals involved in the study or experiment have fully disclosed every aspect of their interest in the research, as well as any potential conflicts of interest; and whereby, according to the norms of privacy and confidentiality, as well as the researcher's rights, complete and open disclosure is made. The complete research records, including data and notes, are kept for as long as is required for post-research monitoring, research evaluation, conducting additional research (whether by the original researcher or not), and making such documents available for inspection by the authorised legal and administrative authorities, if necessary[25].

(D) Form of Consent

The declaration of Helsinki refers to preferably written consent. German law requires that the consent of the patient must either be in writing or to be witnessed independently. In the Republic of Ireland, written consent (subject to certain exceptions) is also required. So far, the UK is considered, there are no particular legal requirements although ethical guidelines endorse the view that consent in writing is preferable. In many cases, the researchers use standard printed consent forms which may refer the patient to a standard information sheet that should be read before signing. Since an underlying principle or of all research is that the subject must be free to withdraw from the trial at any time, the issue of consent remains a live one throughout the currency of any trial.

In India, the subject's consent had to be in writing by using an "Informed Consent Form.[26]"The approval from the ethics committee must be there for both the patient information sheet and the Informed Consent Form.[27]The Informed Consent Form, patient information sheet along with the approval of the Ethics Committee must be forwarded towards the Licensing Authority. A listing of essential parts has to be enclosed in the Informed Consent Form in accordance with the format for the studying subjects.[28]

(E) The Role of Regulatory Mechanisms in obtaining Informed Consent

The informed consent form in writing and any other written information that need to be produced before the subjects or legal representatives must be revised periodically. Any such new information must be relative to the subject's consent. The approval or favourable opinion from the IRB or IEC should be obtained before giving the subject or legally authorized

[25] *Id.* Principle VII
[26] Hereinafter referred as ICF
[27] *Supra* n.18
[28] *Id.* Appendix V of Drugs and Cosmetics Rules 1945.

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representatives any revised information regarding the written informed consent form. This information communicated had to be documented it is relevant for the subject's willingness to continue his or her participation in the trial. The continuation or participation in the trial should be voluntary and neither the investigator nor the trial staff can coerce or unduly influence the subject.

No wording in any of the trial's oral or written materials, including the written informed consent form, should cause the subject or the subject's legally appropriate representative to waive or appear to waive any legal rights, or release or appear to release the investigator, the institution, the sponsor, or their agents from liability for negligence. The prosecutor, or an individual appointed by the investigator, should thoroughly notify the subject, or if the subject is unable to provide informed consent, the subject's legally appropriate representative, of all relevant aspects of the trial, including written information and the IRB/IEC approval or favourable opinions.[29]

The verbal and written information about the trial along with the written informed consent form must be in a language that is non-technical as well as practical. The language used in such communications had to be understood by the subject, the subject's legally authorized representative or the witness whatever information has been procured.

Prior to obtaining the consent from the subject or legally acceptable representative of the subject, the investigator or a person authorized on behalf of the investigator has a duty to provide them enough time to make an enquiry into the trial. This is so important that it enables the subject or the subject's legally authorized representative to take a decision whether to pitch in the trial or not to proceed with the trial.

Prior to the beginning of the subject's participation in the clinical trial, the signature from the subject or the subject's legally authorized representative and by the person who has conducted the discussion for informed consent is necessary in the written informed consent form. The stipulated date is also necessary along with these signatures. Sometimes, a subject or the legally acceptable representative of the subject will have a disability to read or understand the informed consent discussion. In such a case, the facility of a witness who can be impartial and neutral can be availed. The witness has a duty to inform and explain the subject or the subject's legally authorized representative about the trial and what has been discussed in the informed consent discussion. If the subject or the subject's legally authorized subject agrees to the trial after

[29] ICH Good Clinical Practice Guidelines, Available from: http://www.crash2.lshtm.ac.uk/ICHGCP/3IRB-IEC.htm , [Accessed: 20 February 2021].

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explaining it orally by the witness, the signature and stipulated date from the subject, the legally acceptable person and the witness had to be obtained. The signature of the witness in the informed consent form officially indicates that the subject or the legally authorized person of the subject has fully understood about the trial and the witness has explained the discussion in detail and accurately. It also indicates that the subject or the subject's legally acceptable representative has given the informed consent freely and voluntarily.

The informed consent discussion and the written informed consent form has to explain to the person involved in the trial or the legally authorized representative of the person participating in the trial the following details: -

a. The trial is accompanied with research.
b. The objectives of the trial.
c. The trial treatments and therefore the chance for random assignment to every treatment.
d. The all procedures of the trial including any invasive procedures.
e. The responsibility of the subject during the participation in the trial.
f. The experimental aspects of the trial.
g. The reasonable risks and inconveniences for the subject need to be explained to the subject even though it is applicable to an embryo, foetus, or nursing infant.
h. The subject should be made aware about the reasonable benefits of the trial as well as its worthlessness.
i. The availability of any other procedures or courses of treatment for the subject need to be explained in detail including the potential benefits and its risks.
j. The available compensation or treatment for the subject in case of injury during the participation in the trial.
k. The prior discussed payment available to the subject for the participation in the trial.
l. The expected expenditures of the subject while participating in the trial.
m. The participation of the subject is voluntary and the subject has a right to withdraw from the participation in the trial at any time without any kind of penalty or loss of benefits.
n. The monitoring and the auditing authorities, the IRB and the IEC will be granted access to the medical data of the subject participating in the clinical trial for the purpose of verifying the procedures of clinical trial. Such a verification will be within the constraints of confidentiality of the subject in accordance with the applicable laws and

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regulations for the trial.

o. The medical record of the subject will be kept as confidential to be kept away from the public to the extent granted by the applicable laws and regulations. If the result of the trial is published, the identity of the subject shall be kept as confidential.

p. The subject or the subject's legally authorized representative will be provided an information regarding the trial in a timely manner whenever it may become available that may be relevant to the subject's willingness to proceed further with the trial.

q. The persons that need to be contacted during the trial for further information of the trial, the rights of the participants in the trial and the person to be called upon in case of trial-related injury.

r. The termination of the subject's participation in the clinical trial due to the foreseeable circumstances or reasons.

s. The expected tenure of the subject and the participation period of the trial.

t. The probable number of subjects included in the trial for participation.

Before the participation of the subject in the trial, a copy of the written consent form and any other information accompanied with a stipulated date and signature need to be provided to the individual participating in the trial procedure or to the legally accepted representative of that individual. During the process of trial, the individual involved in the trial or the individual's legally acceptable representative is entitled to receive a copy of any updates or any amendments made to the written informed consent form.

In a clinical trial there are individuals or the subject's whose involvement in the trial procedure can only be approved with the consent of the individual's legally authorized persons (e.g., minors, or patients with severe dementia). The trial may be therapeutic or non-therapeutic. However, it is necessary in such a case for the subject to be aware of the trial in a manner understandable by them. If the subject has a capacity to read and be aware of the written consent form in a trial, then the subject has an obligation to provide in the written consent form the signature along with an appropriate date.

Sometimes, the trial of the subject may be non-therapeutical. Non-therapeutical trial has no potential benefits to the person involved in it. Such a trial can only be initiated for a typical type of subjects who are willing to give consent personally. A written consent form is not valid without the signature and date of the person giving the consent. Therefore, it is necessary to have a signature and date in the written consent form.

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Nevertheless, some of the non-therapeutic trials cannot be conducted without the consent from the legally accepted representative. In this case, the non-therapeutic trials with the approval of the representative of the subject can be conducted only by fulfilling the following essential conditions: -

a. The purpose of the trial cannot be met by the subject who gave the consent personally.
b. The risk to the subject by participating in the trial is low.
c. The negative effect of the subject after the participation in the trial is lower than expected.
d. The trial has not been prohibited by any of the existing laws.
e. The inclusion of a particular subject in the trial is based upon the written approval or favourable opinion from the IRB and IEC.

The trials conducted in such a case must be upon a person suffering from a sickness or a condition that has direct resemblance to the outcome of the product usage unless a justifiable exception is made. If the subject is seen as unduly distressed while monitoring the trial process, then such a subject need to be withdrawn without any default. When the anticipatory consent of the subject is unavailable in emergency cases, then the consent of the legally authorized representative must need to be requested and obtained. When the consent of the subject's legally acceptable representative and prior consent of the subject becomes unavailable, the rights, the safety and well-being of the subject need to be protected if proceeded with the trial. The essential requirement is that the measures enshrined in the protocol, documented IRB or IEC's approval must be in accordance with the applicable regulatory requirements. Once achieved these adherences, the very next step is to inform the subject or the subject's legally authorized representative very soon regarding the information about the trial and the consent to proceed with it.[30]

The individual participating in the trial has a right to receive a copy of the completed informed consent sheet. Either the subject or his or her representative can receive the copy. However, the Sponsor's right to receive the copies submitted by the Ethics Committee and the investigator and to be heard before an order is passed by a competent authority is not legally recognized.[31]

[30] Informed Consent form as given in Appendix V of Drugs and Cosmetics Rules, 1945.
[31] Handbook for Good Clinical Research Practice (GCP)," (2002) World Health Organization, p. 10.

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(F) Informed Consent in case of Incompetent Persons

Obvious difficulties arise to those who are legally incompetent[32] persons. Nuremberg Code and Declaration of Helsinki provide only that, "by following the national legislation, the informed consent of a legally incompetent person should be obtained through a legal guardian". The trial involving foetus, pregnant women and human in vitro fertilization, prisoners and children are also included. Certain classes such as students and health care personnel have been identified for special protection because of being susceptible to exploitation. In India, sections 11 and 12 of the Indian Contract Act, 1872[33] covers this aspect. The legality of the consent of the subjects particularly those who gave consent without voluntarily has been frequently challenged. In a trial, some of the subjects are made as a participant by using coercion. These subjects are often considered as the following:- (1) the convicts that are imprisoned, (2) inmates of mental hospitals or domiciliary institutions, (3) patients in "free" or "clinical" hospitals that have an affiliation with the medical, educational, or research facilities, (4) indigent patients, (5) servicemen, and (6) children, including the mentally handicapped and disabled and (7) foetuses. All the subjects mentioned above can be easily coerced. The vulnerable situation of the foetuses allows it to be coerced by using clever and indirect methods. Sometimes, a subject may not fully understand the explanation about the experiment due to the lack of ability to catch up in the mind such as children with disability or mentally ill patients that are admitted into the hospitals or chained in a household. The abuse is often continued due to low public interest in the issue. These vulnerable coerced subjects most commonly comply to the clever and indirect methods instead of making a thoughtful and informed decisions[34]. There are several research populations described as "vulnerable" or what requires additional consideration or protection.' Certain classes such as students and health care personnel have been identified for special protection because of being susceptible to exploitation. However, for developing paediatric drugs, clinical trials must have to be conducted in the paediatric population only.

It is pertinent to note that the researchers have an additional responsibility in respect of the vulnerable trial subjects to ensure that they are not subject to any excessive risks or burdens. The principles of equitable selection of subjects must be satisfied before considering questions of consent. The researchers must ensure that the research would lead to the betterment of this

[32] Lacking the legal capacity to consent on their behalf (children, prisoners, pregnant women, mentally disabled persons) also educationally or economically disadvantaged persons.
[33] Act No. 9 of 1872, 1 September 1872.
[34] M. Cherif Bassiouni, Thomas G. Baffes, John T. Evrard, "An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation", The Journal of Criminal Law and Criminology (1973) Vol. 72, No.4 pp. 1597-1666 Available from: http://www.jstor.org/stable/1143248 [Accessed: 13 February 2021].

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class also they are not subject to excessive risks or burdens.

Another controversial issue is that the certain types of experiments are often blocked by the laws as it is opposed to the public policy. The law regards such experiments as unacceptable to the people which may make them expose themselves into a high degree of danger. There is no relevant case law applying this principle, but some commentators have suggested that it would make consent to a Phase I trial invalid.

IV. JUDICIAL PRONOUNCEMENTS

The principles articulated by Lord Scarman in the case of *Sidaway* v. *Board of Governors of Bethlehem Royal Hospital*[35] form the cornerstone of informed consent. These are:

- The informed consent is a concept that a person who is in adulthood and sound mind can choose as a right of his or her own along with what shall be happening to that individual's body.
- Consent is that the informed exercise of a choice which entails a chance to gauge knowledgeably the choices available and therefore the possible risks upon each of the participating subjects.
- The Doctor has a duty to disclose all the available material risks involved in the trial. The material risks are determined by conducting the test on the patients. This test is relevant to determine the reasonable significance of the patients involved in the test and to come into a decision upon the kind of treatment advice that need to be given.

Justice Cardozo in the case, Schoendorff v. *Society of Newyork Hospital* has explained that the duty of the physician to get a patient's consent is regarded as justice in the following words.[36]

Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who operates without his patient's consent commits an assault for which he is liable for damages. This is true except in cases of emergency, where the patient is unconscious and where it is necessary to operate before consent can be obtained.

In the celebrated Canadian case, *Halushka* v. *University of Saskatchewan*,[37] the court held that for consent to research to be valid, it would have been given after the complete disclosure of the facts in the case. In this case, the patient had been wrongly reassured that the experimental drug was safe and had been used many times before, and his consent was therefore invalid.

[35] (1985)1 All. E.R. 643
[36] 105 N.E 92,93 (N.Y.1914)
[37] (1965) 53 DLR 436

In *Diaz v. Hillsborough County Hospital Authority*[38],the case was considered as a class-action lawsuit filed on behalf of three hundred and eighty three pregnant women who were subjected to medical experiments, such as amniocentesis without obtaining their express or implied consent. The researching team used consent forms in English language but many of the women were not able to speak the English language. Some of the pregnant women gave their consent to be involved in the research at the time of admission to the hospital for labour or while drowsy or delirious purposes. To settle the case, the hospital authorities agreed to make payments to the plaintiffs and change their research procedures.

In *Hyman* v. *Jewish Chronic Disease Hospital,*[39] the court refused to take into consideration a petition filed by the director of a hospital membership corporation to grant the access to inspect the medical charts of twenty-two cancer patients who had been injected with live cancer cells to determine if their bodies make any response to such cells and whether it was the same as for the healthy patients. The Petitioner argued in the court that the patients involved in the procedure or research were either incompetent or has not given the adequate consent. Significantly, the court involved in this case noted that it is necessary to have a written informed consent for similar kind of experiments.

In *Kazimowltz* v. *Dept of Mental Health,*[40] the court held that the mentally ill patient was unable to give an involuntary informed consent for the purpose of an experimental psychosurgical procedure. In this case, the patient involved had been committed to a state hospital functioning under the Michigan's criminal sexual psychopath law. The convict and his parents provided their signatures in the consent forms which had allowed the convicted offender to undergo the experimental procedure designed to control the violent behaviour that has been seen in the persons suffering from uncontrollable aggression. The suit was brought into the court on behalf of the patient by an attorney to seek a writ of habeas corpus on grounds that the patient was being illegally detained for experimental psychosurgery. The attorney presented two issues in the Court. The first issue was whether an involuntarily detained mental patient has the capacity to give an informed consent to have an experimental psychosurgery[41] which may alter his or her thoughts, emotions, or behaviour. The second issue was whether; the State Department of Mental Health under its jurisdiction can conduct an experimental psychosurgery upon the involuntarily confined mentally ill patients in hospitals by assuming that such persons may give

[38] 2000 US Dist. LEXIS 14061
[39]21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964)
[40]No. 73·19434·AW. (Mich. Cir. Ct.)
[41]Psychosurgery is the treatment of a psychiatric disorder using surgical techniques to destroy brain tissue and is now rarely used. Available from: < http://www.minddisorders.com/Ob-Ps/Psychosurgery.html#b#ixzz2UC94Ojpi>.[Accessed: 01 February 2021].

their consent. The court by taking these issues into consideration had answered the first issue in negative sense and therefore did not proceed to the second issue. The Court from the Nuremberg Standards identified the three criteria for an informed consent. They are as follows: - competence of the subject, knowledge by the subject, and voluntariness.

In *Grimes* v. *Kennedy Krieger Institute*[42], the court held that Kennedy Krieger Institute had an obligation to give warnings to the subjects' parents of dangerous lead levels and is also duty bound to obtain a legally effective informed consent from the parents of the subjects. The Appellate Court in this case also discussed any legal standards that are applicable for including children in research that offers no direct benefit to the children sometimes also called as non-therapeutic research. However, later on, the court changed its previous opinion on the issue of paediatric research because of its inconsistency with the federal rules and regulations that allows the children to voluntarily participate in the research which may not have any benefits to them and only minimum amounts of risks while participating in the research[43].

Robertson v. *Mcgee*[44] the case is very important as it is believed to be the first case in which the names of the individual members of the IRB have been incorporated as Defendants in the United States legal history.[45]Prior to this case, the names of the IRB had been brought into the Court but they were collectively incorporated as Defendants. This case was also an important case in the United States legal history because a federal district court had earlier refused to recognize the right to be treated with dignity enshrined in some of the international ethics standards such as the Nuremberg Code. In this case, the plaintiffs alleged that the research team had failed to fully inform them about the risks involved in taking the vaccine and the research team often misrepresented the vaccine as a cure for cancer. The plaintiffs also alleged that the research team enrolled unsuitable subjects and failed to monitor them repeatedly. Nevertheless, only in July 2002 that some of the defendants involved in the dispute had reached into a settlement with the plaintiffs.[46]

The English courts and U.S courts have accepted that the need for fully informed consent is greater in the context of CTs than it is in treatment. This requires the researchers to tell the

[42] 782 A.2d 807(Ct of Appeals, Md 2001)

[43]*Wendler D, Risk standards for pediatric research: Rethinking the Grimes ruling, Kennedy Institute of Ethics Journal 14 (2):187-198 (2004) Available from: http://muse.jhu.edu/journals/ken/summary/v014/14.2wendler.html>. [Accessed 22 March -2021]*

[44]Robertson v. McGee. No 01CV00G0H (M) (ND Okla filed January 29, 2001), Sherman, Silverstein, Kohl, Rose and Podolsky Law Offices, Available from: <.http://www.sskrplaw.com/gene/robertson/complaint.html>. [Accessed 25 March 2021].

[45] Hereinafter referred as the U.S

[46] M.Mello, D.Studdert and Brennan T, *The rise of litigation in human subjects research,* Ann Intern Med .publishers, London(2003), pp.40-45

subjects that they are involved in research, and possibly give those details of research design, but this has never been tested in court and would seem unlikely, in the light of courts' reluctance to permit consent issues to raise outside the law of negligence. While it is often dangerous to rely on overseas decisions, it can be looked into if there are reasons to believe that such decisions can be adapted to Indian circumstances.

In *Paschim Bengal Khet Mazdoor Samity* v. *State of West Bengal,*[47] the court held that the subject involved in the trial or research has a legal right to receive the information regarding the recording of medical data that is relevant for the subject. The subject also has a right to receive any update or status regarding his or her medical condition. The Doctor has a duty and obligation to give warnings to the patient and let the patient decide for himself/herself whether to submit or not to the proposed medical treatment.

Swasthya Adhikar Manch[48]on February 2012 filed a Public Interest Litigation in the court after the news circled around the country regarding the illegal clinical trials and the alleged illegal and unethical drug trials conducted by the MGM Medical College in Madhya Pradesh upon the mentally disabled patients. The Supreme Court of India by interfering into the matter has clearly indicated that the Madhya Pradesh government has failed to furnish proper mechanisms to curb the functioning of illegal clinical trials conducted by the multinational companies and its rackets. The Supreme Court further directed the government to deal with issue as quickly as possible. The court instructed the Health Secretary in the Health and Family Welfare Ministry of Madhya Pradesh to directly monitor every clinical trial conducted upon the human beings by using drugs and to ensure that whether the statutory procedures are followed by the testing companies and agencies. The order of the Supreme Court had also stated that "until further order by this Court, clinical trials of the new chemical entity shall be conducted strictly in accord with the procedure prescribed in Schedule 'Y' of Drugs & Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health & Family Welfare, and Government of India[49].”

V. FLAWS IN THE INFORMED CONSENT PROCESS

Several observations and findings generated from media reports and social organizations give a clear picture that the informed consent requirement is not being complied with.

[47] A.I.R. 1996 S.C. 2426

[48] A Non-Governmental Organization at Madhya Pradesh.

[49]Meera Kay, “Indian Supreme Court tells government to act on illegal clinical trials”, Available from: <http://www.ahrp.org/cms/content/view/898/84/ >[Accessed: 05 February 2021].

(A) Controversy on trials in Indore

Recently, there was a report that the doctors of the government medical college and the private practitioners in Indore are conducting drug trials on the body of mentally challenged patients. This report had caused the public uproar.[50]The report alleged that from 2008 to 2010 that is, for two years, trials were conducted upon patients by disregarding the ethical guidelines. Subsequently after the incident took place, the Government of Madhya Pradesh fined the doctors involved in it with a levy of Rs 5000 for each of the doctors[51]. This amount as a fine has been widely criticized for its partiality and insufficient punishment. Furthermore, the incident reported in several newspapers, journals and articles had raised a substantial of questions among the masses. Some of the questions raised were the role of independent or commercial ethics committees, the role of improper consent and the dangers exposed to the subject as well as the issue of government doctors practicing in private hospitals and clinics.

One of the world's most reputed medical journals - Lancet –on Saturday has come up with a report in its journal which has explained about the violations of ethical principles and guidelines in clinical trials conducted in the state of Madhya Pradesh. The report also stated that this incident has clearly shown us the loopholes in the country's regulatory system. In the report, the representative of WHO to India, Nata Menabde, acknowledged the fact that the vulnerable populations in Madhya Pradesh were exploited and the process of informed consent were not adequately followed in that state[52]. Several Complaints were filed with the State and National Human Rights Commissions and Drug Controller General of India (DCGI) last year following which Economic Offence Wing[53] investigated some of the doctors at Maharaja Yeshwantrao Hospital in the city and found that 73 clinical trials were undertaken on 3300 patients, including 1833 children for various testing purposes. Out of this number, a total of 81 patients inclusive of 18 children were reported with severe injuries and deaths as a result of their participation in the trial. The enquiry conducted upon the complaint filed by the health activists also revealed that the volunteers involved in the trial had not given their consent in the informed consent form due to the usage of English language in the form.[54]

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[50]Rajalakshmi TK., "Criminal Trials", The Frontline. 2012 Jan-Feb;29(2) Available from: http://www.frontlineonnet.com/fl2902/stories/20120210290203300.htm [Accessed: 05 February 2021].

[51]Ghatwai M., "Drug trials: Panel for stringent action, doctors fined 5,000 each". The Indian Express. 2012. Jan 2, Available from: http://www.indianexpress.com/news/drug-trials-panel-for-stringent-action-doctors-fined-rs-5-000-each/894681/2 [Accessed: 05 February 2021]. 02.01.2021.

[52] Ashish Gaur, "Ethical Violations expose chinks in regulations", The Times of India, Feb 5, 2012, Available from: <http://articles.timesofindia.indiatimes.com/2012-02-05/indore/31026410_1_clinical-trials-drug-controller-general-dcgi >[Accessed: 06 January 2021].

[53]Hereinafter referred as EOW

[54]*Ibid.*

(B) Child Deaths During Clinical Drug Trials

In Bhadrachalam, most of the girls were the residents of ashram paathshalas (boarding schools). The majority of the girls selected for the project were having a selection criteria. Most of the girls were having separated parents. This has made the project so simple that the parents cannot monitor and respond to any kind of bad effect towards the health of the selected girl child. Moreover, lack of monitoring the child has led to the project initiators to have an added advantage. It allows them to skip the process of the consent from their parents. Majority of the girl children were within the tribal communities with their parents' income coming from the agricultural works. The administration of the vaccines was done by camping in the hostels and school premises.

Most of the times, the wardens or the guardians of these residential schools were asked to provide their consent or permission for vaccinating the children while the parents of the children knew nothing about the project or vaccination.[55]The guardians or the wardens kept about the vaccination scheme or project as secret or uniformed to their parents. It is considered as a violation of ethical norms and guidelines to vaccinate the children without informing their parents who are considered as their natural guardians. The selected girls were given HPV Immunization Cards. These cards were written in English language which makes the girls or their parents understand the script as most of them do not know the English language. Furthermore, the project had been considered as public immunization program instead of part of a research study by the wardens, teachers and students of the residencies and schools. The research study was conducted by the investigators by misrepresenting the fact that the vaccination was a part of the government scheme to provide free of cost an expensive vaccine that could prevent the 'uterine' or 'cervical cancer'. They also stated that this vaccine is unaffordable to buy by most of the girl child or parents. By misrepresenting the children and their parents, the research teams were able to bring several of the parents into vaccination camps conducted by them as a part of their study. The mother of the one girl child often said that, "Since it was a vaccine being given by the government, we all trusted it blindly and considered it reliable, like any other vaccine that is given in the immunization programme". The research teams in the vaccination camps also stated to the participants in the camps that the vaccination taken by their children will provide life-long protection without affecting their fertility.[56]

[55]Adithya Nigam, "Ethical violation of HPV Vaccination Trials in India", Available from: http://kafila.org/2010/05/17/ethical-violations-of-hpv-vaccination-trials-in-india-sama/.[Accessed: 05 February 2021].
[56]*Ibid.*

As a result of the vaccination, many of the girl child still suffers from diseases such as abdominal pain, headaches, dizziness, and fatigue. There were frequent reports that because of taking the vaccination, the girl child was showing symptoms of early menstruation, menstruation cramps, heavy bleeding, severe mood swings and irritation. No systematic follow up or monitoring has been carried out by the vaccine providers. On 22nd April 2010, the Ministry of Health and Family Welfare finally provided a statement that the earlier project titled "HPV Vaccination Project" was a Phase IV post-marketing clinical trial and post licensure operational research study. The ICMR on 29th April admitted that the ethical guidelines of ICMR was disregarded during the process of the clinical trial.[57]

(C) The nod from Ethics Panel – All India Institute Medical Science

Over the last two and a half years, as many as 49 babies have been subject to death at the All-India Institute of Medical science[58] while being made as a participant to clinical trials for testing new drugs and therapies. AIIMS had stated that for conducting the trials, it had taken approval from the AIIMS ethics committee, the Health Ministry Steering Committee (HMSC) on ethics and the national ethics committee of the ICMR. It is doubtful that whether most of the parents and their children could understand what a clinical trial means because most of the patients visiting or admitting in the AIIMS are extremely poor and illiterate.[59] The Lucknow bench of Allahabad High court has even sought the names of foreign pharmaceutical companies especially those involved in the clinical trial as a part of an investigation or research study.

(D) Unethical Trial held at Regional cancer centre, Thiruvananthapuram

On November 1999, 25 people with oral cancer visited the Regional Cancer Centre[60] in Thiruvananthapuram. This centre was functioning under the Kerala Government. These twenty-five people were given an experimental drug, the chemical tetra-O-methyl nordihydroguaiaretic acid or tetra glycine nordihydroguaiaretic acid, when there was an already established treatment for their condition. The issue was first brought into public attention by some of the patients and Dr V.N. Bhattathiri of RCC which made it clear that the participants in the trial were not having any knowledge that they were taking an experimental drug as a part of the trial. They were also unknown that an established treatment was not granted to them for their disease. Later, it was known that the trial itself was conducted without any approval from the Drugs Controller of India.

[57] *Supra* 24.
[58] Hereinafter referred as AIIMS
[59] Kounteya Sinha, Times of India, 18th August 2008.
[60] Hereinafter referred as RCC

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On 30th July, 2001, the Baltimore-based Johns Hopkins University[61]stated to the medias in the United States that the clinical trial was conducted without obtaining the approval from any of its Institutional Review Boards.[62] In an interview with a U.S. newspaper on July 31, the member of the faculty, Dr RuChih C. Huang, a Professor of Biology at the JHU since 1965, said that she had no knowledge that the University should seek the approval from internal review boards for conducting an experiment abroad. She also stated that she had conducted the clinical trial because it had already gained an approval from a "similar panel" in the RCC.[63] The most significant statement stated by Huang in the newspaper was that her "study was funded by $2 million from 'Biocure Medical of Minnesota'" and that the "Hopkins holds a patent on the drug and could profit if the company can bring it to market as a cancer treatment". This makes it clear that the Hopkins could be able to make a profit and huge returns if this drug is brought into the market within a span of four or five years.

Although the RCC had claimed that the drug injected had substantially reduced the brain tumour and there was no harm done to those 25 people with oral cancer. However, most the patients were sent home after injecting the drug and removing the tumour and there was no trace of continuous check upon the patients.[64] The report from the Gazette Online indicates that the letter of intent for taking the drug was signed on 27th July 2000 after the two months of the trial that took place in the RCC. According to Nina Siegler from the Office of Technology Transfer, “one of the first objectives of the new company will be to design and conduct FDA (Food and Drug Administration)-approved clinical trials of these substances”. This statement made by Nina Siegler questions the approval status of the trials conducted by the RCC which had already been conducted upon the patients.

The report that came in July 2000 in the JHU's online newspaper also said that some of the Universities holding a patent right or license, can grant a newly formed company an exclusive license to use those inventions made by the Universities and "there will be contracts between the university and the company for Hopkins to continue work on new drug analogues and clinical development". The cancer centre’s Finance Manager (Projects) K.R. Bhaskaran Nair because of the JHU’s denial in accusation of funding the RCC for its clinical trial issued a press statement on 3rd August to the medias in the following words: "A section of the media has reported that the M4N clinical trials at the RCC were not funded by the Johns Hopkins University. The RCC denies this baseless news report. There is very clear documentary

[61] Hereinafter referred as JHU
[62]Hereinafter referred as IRB
[63]R.Krishna Kumar, “Drug Trials and ethics”, Frontline, Vol 18-Issue 17, Aug.18-31,2001, pp 4-6.
[64]*ibid*.

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evidence that RCC had received funds from Johns Hopkins University for the clinical trials conducted under the leadership of Dr RuChih Huang (Ordering bank: First Union National Bank, New York; Ordering customer: Johns Hopkins University, Baltimore). This statement is being issued to remove the wrong impression that people may have because of the news report."[65]

Dr. Parvesh Parikh of the Tata Memorial Hospital in Mumbai, who is part of the one-man commission appointed by the State government to investigate the matter, also said that he had documents proving that funds had been approved with JHU's approval and that the documents had been signed by the university's "treasurer". On August 10, when counsel for one of the patients, who had previously approached the Kerala State Human Rights Commission, produced "RCC papers" before the Dr Parvesh Parikh inquiry commission, the holes in the jigsaw assumed a serious dimension. Counsel claimed that the injections were to blame for the deaths of two patients who died less than 50 days after participating in the trial in early 2000.After deposing before the commission, relatives of a 60-year-old woman patient suffering from "terminal malignancy" told reporters that the doctors had asked if they would be able to include her in a new project of the contract research organisation (with which the JHU had signed an agreement in 1998) that would provide her with five doses of the experimental drug for free that amounts to Rs.10,000. However, the woman's condition had deteriorated before taking the fifth injection.

(E) Diabetes drug tested on humans before toxicology[66] studies completed

The multinational company Novo Nordisk conducted a multi-centric Phase III clinical trial by using a diabetes drug in the year 2002. The study was conducted in the human beings without gaining the result of the studies conducted upon the animals. The report of the study indicated that the drug named "Ragaglitazar" made tumours in the urinary bladder of rats. These tumours in the urinary bladder of rats should be known before Phase I, Phase II and Phase III trials of the drug. The drug Ragaglitazar was developed from India at the Dr Reddy's Laboratories. This laboratory was based in Hyderabad. The drug was further licensed to Novo Nordisk who had conducted the clinical trials. A total of 2730 people were included in the clinical trial. Out of 2730 people, 650 people was from North America, 200 from Latin America, 100 from Australia and New Zealand, 800 from the European Union, 250 from the non E.U. Europe and 550 from the Asian continent. Out of 550 from Asia, 130 people were from India who had taken part in

[65]*Id*. pp. 7.
[66]Toxicology is the study of the adverse effects of chemicals on living organisms. It is the study of symptoms, mechanisms, treatments and detection of poisoning, especially the poisoning of people.

the clinical trials across eight centres of India. According to the report, about half of these people had received the experimental drug named "Ragaglitazar".

(F) Drug Promotion as Research

The Mumbai based Sun Pharmaceutical Industries Limited in the year 2002 launched a promotional research program for their drug Letrozole. Letrozole is said to be an anti-cancer drug. The private doctors involved in the program were asked to make Letrozole as a prescription for curing the women from cancer that impacts their fertility for ovulation induction. The doctors prescribed the drug to more than 400 women. The company published the doctors' reports to other doctors' by using their network of medical practitioners and representatives. Subsequently, the off-label prescription of drugs was banned by India. This ban prompted the Indian Medical Association to launch several campaigns to permit the off-label prescription. A similarity to this trial is the trial conducted in West Bengal in which 790 poor illiterate women were subject to use the vaginal pellets of erythromycin as contraceptive agents. Numerous instances indicate that many of the trials took place without satisfying the requirement of informed consent.

VI. CONCLUSION

This paper has shown that, while informed consent provides an important statement of a patient's right to self-determination, case studies reveal that trial subjects are seen denied this right to a major extend. There are various important initiatives to promote the lucidity and accessibility of safe and effective clinical trials. The obligation to create a recording of the data and the registration of the trials prior to their commencing period are one among them. These initiatives are achieved through goodwill and collaboration of the research sponsors involved in the clinical trials. Majority of the countries in this world have neither the legal framework nor the regulations to provide access to the information about the therapeutic products.[67]

However, these operate only in marginal areas and are more concerned with subjecting professionals to market forces[68] then with the quality of consent to care. In India, for judging the ethical principles, it is always difficult to follow the following four principles of ethics i.e., beneficence, non-malfeasance, patient autonomy and justice. It is mainly because tremendous pressure exists to meet the basic needs of people such as food, housing, education, and health. The sanctity of the life is less than the standard or quality of life in bio ethical decisions. People

[67] TrudoLemmens and Candice Telfer (2012). Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency. American Journal of Law and Medicine,38: p 64.
[68]J.Montgomery, "Patients First: The Role of Rights" in K.W.M.Fulford, S.Ersser, and T.Hope (eds.), Essential Practice in Patient-centered care, Oxford University Press, New York (1st edn.,1997),pp.142-52.

are faced with ethical dilemmas because of such judgments, which are usually resolved in the light of cultural norms dealing with socio-economic considerations.

Doctors are often revered as gods, and their judgments are accepted as gospel truth without question or any doubt. This has placed a great deal of pressure on the physician to conduct himself in an ethical, right, and truthful manner when working with his test subjects. The hope is that by training clinical researchers further, we can reduce these flaws and improve the rigour with which we perform clinical trials. It is not difficult to get informed consent when the people are literate. When the doctors are considered as gods by the illiterate and uneducated patients, it is difficult to receive an informed consent. It is an unethical practice to get volunteers for the trial by giving them the rewards or financial incentives.

The principal investigator and his colleagues should ultimately decide the inclusion conditions for participants, including their ability to give informed consent. Incidentally, the ICMR provides the rights and guidelines available to the subject while participating in the trial. Clinical trial knowledge is a critical tool for drug and medical device creation, and it should be accepted as a basic component of the right to health. The protection of a person's physical and mental integrity, as well as their health empowerment, necessitates immediate access to knowledge. There is also an undeniable connection between clinical trial details and the right to health, which can be used to foster a strong knowledge framework based on open data.[69]

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[69]TrudoLemmens & Candice Telfer (2012). Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency. American Journal of Law and Medicine,38: pp 63-65.

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 [ISSN 2581-5369]