ROLE AND FUNCTIONS OF ETHICS COMMITTEE IN CLINICAL TRIAL: ISSUES AND CHALLENGES

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Abstract

On March 19, 2019, New Drugs and Clinical Trials Rules, 2019 have been introduced. Under these rules, ethics committee plays significant role in clinical trial. This committee is established by the researcher who intends to conduct clinical trial. The major functions of ethics committee are to give and review the approval to the clinical trial. Ethics Committee is entrusted an obligation to ensure the conduct of clinical trial in the interest of the rights, safety and well-being of the research participant as mentioned in the Good Clinical Practices Guidelines and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. Another major duty of Ethics Committee is to submit detailed report to the Central Licensing Authority in case any serious adverse event occurs during the clinical trial and to pass order for the discontinuation or suspension of trial for the violation of the rights, safety and well-being of the research participant. In furtherance of this, several other duties are fixed under the New Drugs and Clinical Trials Rules, 2019 such as to furnish relevant documents to the authority or allow authorized person on behalf of Central Licensing Authority for the inspection of Clinical Trial etc. The major concern for the discussion is the power to constitute the ethics committee and their legal validity in the context of fundamental principles of law. Lack of mechanism to check the independency of the members or any vested interest in the clinical trial is the issue to be discussed. Lack of detailed procedure and powers to protect the rights, safety and wellbeing of the research participant as mentioned in the Good Clinical Practices Guidelines and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 is not observed in the New Drugs and Clinical Trials Rules, 2019 are the major lacunas that exist in the rules. Researcher intends to study the relevant provisions for the protection of the rights of the research participant in Good Clinical Practices Guidelines and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 and its implementation in the New Drugs and Clinical Trials Rules, 2019 and to provide solutions to meet this exigency.

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I. Introduction

LATIN TERM '*Primum non nocere'*, is the basis of the medical profession since ancient times. Simply, it means 'first do not harm'. It is well recognized that doctors or medical professionals should try their best not to harm the patients even the treatment or procedure is in the interest of the patient. Gradually, the scenario is changed with the advancement of medical science. Medical science has adopted liberal approach with an objective to prevent and cure the diseases and invented various advanced medical treatments. The Modern Medicine has evolved over the last few centuries with great innovations in diagnosis and medical treatment. In this context, globally, as of 10:37 am CEST, October 22, 2020, there have been 40,890,712 confirmed cases of COVID-19, including 1,126,351 deaths, reported to WHO. Entire world is facing the challenge of the spread of corona virus including India. In India, 7706946 (citation 2) cases so far reported till now. Almost all the developed and developing countries are largely affected due to the wide spread of the Covid-19. Therefore, to curb and control the transmission of covid-19 pandemic, across the globe, almost all the countries are engaged in the search of a safe and effective vaccine to prohibit the spread of the virus and medicine to cure the patient after infection. In this scenario, urgently clinical trials will be conducted with an object to determine the safety and efficacy of the proposed vaccine against the covid-19. Essentiality of clinical trial cannot be ignored considering the large affected people in the world but it should not be at the cost of the rights of the violation of the research participant. Clinical Trial has been an inevitable part of the modern medicine which has played a very pivotal role in the advancement of modern medicine.

The origin and history of clinical trial can be traced back to Egypt. From 2850 BC to 525 BC, an Egyptian medicine by the name of the Egyptian Imhotep was prevailing. The Greek Hippocrates has been considered as the father of modern medicine.[1] At a global level, history recorded numerous and well-known instances of the clinical trial such as Babylonian, James Lind's case, Tuskeegee experiment, Nuremberg Trial, *etc.* After the tragic Nuremberg incident,

[1] John I. Gallin, Frederick Ognibene, *et.al.* (eds.), *Principles and Practice of Clinical Research*, 1 (Elsevier Science, London, 2007).

serious necessity of realization of rules had forced the world to incorporate common rules to regulate clinical trial and 'Nuremberg Code' took birth.

Nuremberg Code is the first International Document pertaining to Clinical Trial which encompasses the new standard of ethical behavior during the trial. The doctrine of informed consent is well recognized in the code which gives protection to the right to self-determination of the research participant. The principles enunciated in the code have been widened in codes of medical ethics at International and National level. In fact, the object of these codes is to regulate and protect the interest of the research participant in the clinical trial.

At the International level, declaration of Helsinki, International Code of Medical Ethics, Belmont Report, and International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002 *etc.* are ethical guidelines provided regulatory mechanism to conduct clinical trial at the national level. Consequently, in India, National Ethical Guidelines for Biomedical Research on Human Participants, 2017 and Good Clinical Practices Guidelines, 2000 are issued by the Indian Council of Medical Research and Central Drugs Standard Control Organization (CDSCO) respectively. These two ethical guidelines cover objectives and principles laid down under Helsinki Declaration and International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002. One of the major objectives of all the guidelines is to give preference to the rights of research participant over the other subjects. To fulfill these objectives, ethical guidelines have provided provision for the constitution of research committee or ethics committee due to complexity of different procedures in clinical trial. Accordingly, the New Drugs and Clinical Trials Rules, 2019 issued under the Drugs and Cosmetics Act, 1940 lays down the provisions for the constitution, powers and functions of Ethics Committee. Ethics Committee is the supervisory body to inspect the observance of ethical guidelines and New Drugs and Clinical Trials Rules, 2019 during the clinical trial.

Due to inherent limitations of the law and multifaceted procedure involved in clinical trial, it is essential to have an independent mechanism to supervise and administer the entire procedure of clinical trial. Constitution of Ethics Committee in clinical trial is the answer to redress this issue. Defined roles and functions of Ethics Committee are very crucial in this context. But, there are some lacunas that exist in the current enforceable New Drugs and Clinical Trials

Rules, 2019 regarding the role and functions of Ethics Committee in India which seriously affects the objectives of the ethical guidelines and against the basic concepts of law. In fact, it creates an opportunity to violate the rights of the research participants in the clinical trial which is a matter of grave concern from the legal perspective. This issue attracted Researcher to study further in depth. Researcher, in this paper attempts to study the prevailing ethical guidelines at International and National level and New Drugs and Clinical Trials Rules, 2019 in order to find out the legal issues involved in the constitution, powers and functions of Ethics Committee and their impact on the fundamental principles of law with the material solution to redress these issues.

II. Position at International Level

Role of Ethics Committee in Helsinki Declaration

Nuremberg Code[2] is the First International Documents which contains fundamental principles to be observed during clinical trial. Afterwards, Helsinki Declaration[3] came into existence which declares the detailed procedure to be followed during the clinical trial procedure. Helsinki Declaration has laid down various provisions for the constitution, powers and functions of the Independent Committee for the medical research. This committee is established with an objective to observe closely and critically, the ethical guidelines mentioned in the Helsinki Declaration. Also, the Independent Committee has a right to monitor ongoing trials. The protocol should be submitted for the consideration, comment, guidance and for the approval of the Independent Committee. Such committee is under an obligation to communicate higher authority about the serious adverse event if occurred during the trial.[4]

Function of Ethics Committee under the International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002

[2] The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

[3] World Medical Association has adopted principles as Declaration of Helsinki in 18th WMA General Assembly, Helsinki, Finland, June 1964 which contains the Ethical Principles for Medical Research Involving Human Subjects.

[4] World Health Organization, *Declaration of Helsinki,* 79 (4), 2001, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, (Paragraph 13), *available at:* https://www.who.int/bulletin/archives/79(4)373.pdf (last visited on Jan. 10, 2019).

The aims of the guidelines are to protect humans in research activity and to provide safeguard the rights and welfare of humans. To achieve these objectives, ethics committee is obliged and made it responsible for safeguarding the rights, safety, and well-being of the research subjects.[5] Research ethics committees must review research protocols according to the principles set out in these Guidelines.[6] The provisions of basic responsibilities of Ethics Committees are:

Constitution of Ethics Committee: Research Ethics Committee may function at the institutional, local, regional, or national levels, and in some cases at the international level. They must be established in accordance with rules set by a national or other recognized authority. Regulatory or other governmental authorities must promote uniform standards for committees within a country.[7] Ironically, guidelines indicate the power to constitute Research Ethics Committee will be decided by the national or any local body. Guidelines further clarify the qualifications of the Research Ethics Committee and duties to be performed in an independent manner.

Duty to decide the safety and need of drugs: The committee is empowered to determine the proposed interventions, particularly the administration of drugs and vaccines or the use of medical devices or procedures under development, are acceptably safe to be undertaken in humans or to verify that another competent expert body has done so. The prime responsibility of the Ethics Committee is to observe the objective of the clinical trial before according approval to the protocol and strictly follow the safety norms required before the introduction of drugs to human participants. Precautionary and safety measures to be adopted, analysis of risks and benefits, merits and demerits of the participation, contents of the informed consent form *etc.* are expected to be strictly observed by the Ethics Committee. Briefly, entire clinical trial is conducted under the control and supervision of the Ethics Committee.

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[5] The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), *International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002,* Approved in November, 2016. (Commentary on Guideline 2, Pg.16), *available at:* https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf Guidelines 23 (last visited on Jan. 08, 2019).
[6] *Id.,* at 87.
[7] *Ibid*.

***Duty to observe the implementation of the ethical guidelines*:** The Ethics Committee is obligated to ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and in practice. Respect for persons, beneficence, non-malfeasance and justice are the fundamental principles of the ethical guidelines to govern clinical trial. These four principles are reflected in the ethical guidelines. The details of the object of the trial, protocol, informed consent form and process to obtain it, analysis of risk and benefits, rights and duties of the research participant etc. are described in the International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002, National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 and Good Clinical Practices Guidelines. Ethics Committee is directed to strictly monitor all requisites during the clinical trial.

***Duty to observe standards and conditions of research sites**:* To consider the qualifications of the investigators, including education in the principles of research practice, and the conditions of the research site with a view to ensuring the safe conduct of the trial.[8]

At International level, Helsinki Declaration and International Ethical Guidelines for Biomedical Research involving Human Subjects, 2002 has provided mechanism and procedure to protect the interest of the research participant of the clinical trial through the establishment of Ethics Committee. It is expected that the Ethics Committee will function independently and impartially and will attempt to give justice to the research participant in case any serious advent event happens.

III. Position in India

In consonance with the ethical guidelines issued at the International level, in India, Good Clinical Practices Guidelines and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 are issued by the Central Drugs Standard Control Organization (CDSCO) and ICMR respectively. The provision for Constitution of Ethics Committee has made it mandatory.

[8] *Id.,* at 18.

Recently, the provision to constitute 'Ethics Committee' has been defined under rule 2(0) of the New Drugs and Clinical Trials Rules, 2019. "Ethics Committee" means, for the purpose of, Clinical trial, Ethics Committee, constituted under rule 7 and registered under rule 8. Here, we will discuss in brief the provisions mentioned under the ethical guidelines framed by CDSCO and ICMR.

Good Clinical Practices Guidelines, 2002

Good Clinical Practice Guidelines has been issued by the Central Drugs Standard Control Organization (CDSCO). Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects.[9] The purpose of this guideline is to carry out scientific and ethical clinical trial and to ascertain the applicability of two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated.[10] The constitution and object of Ethics Committee is described in the GCP Guidelines as "An independent review board or committee comprising of medical/scientific and non-medical/non-scientific members, whose responsibility is to verify the protection of the rights, safety and well-being of human subjects involved in a study. The independent review provides public reassurance by objectively, independently and impartially reviewing and approving the "Protocol", the suitability of the investigator(s), facilities, methods and material to be used for obtaining and documenting "Informed Consent" of the study subjects and adequacy of confidentiality safeguards.[11] Further, the basic responsibilities are imposed upon the Independent Ethics Committee to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity.[12] In addition to this, IEC is responsible to protect the dignity, rights and wellbeing of the potential research participant and to ensure the universal ethical values and international scientific standards in the clinical trial.[13] National Ethical Guidelines for

[9]Central Drugs Standard Control Organization, 5 "Good Clinical Practice Guidelines, 2001".
[10] *Id.,* at 6.
[11] *Id.,* at 8.
[12] *Id.,* at 21.
[13] *Ibid.*

Biomedical and Health Research involving Human Participants, 2017 contain similar provisions in relation to Ethics Committee, their powers and functions as well.

In short, after the study of the constitution and functions of Ethics Committee under the New Drugs and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 has focused on the major role of Ethics Committee. The aim and functions of the introduction of Independent Ethics Committee is to ensure the protection of the rights, interest and wellbeing of the research participant as well as to carefully observance of ethical standards during the clinical trial. Nevertheless, several legal issues are yet to be resolved in the interest of the research participant.

Discussion on the Constitution of Ethics Committee under New Drugs and Clinical Trials Rules, 2019

The New Drugs and Clinical Trials Rules, 2019 (rules) has been introduced to regulate clinical trials in India. These comprehensive rules are applicable to the new drugs, investigational new drugs for human use, clinical trial, bioequivalence study, bioavailability study and ethics committee.[14] Constitution of Ethics Committee (EC) made is compulsory and required it to be registered under rule 8 of the rules.[15] Rule 6 provides the constitution of Ethics Committee by the person whosoever intends to carry out clinical trial.[16] The minimum numbers of members of the Ethics Committee is seven and members from medical, non-medical, scientific and non-scientific areas with at least, one lay person, woman, legal expert, one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.[17] Also, fifty percent members of the Ethics Committee should not be affiliated to the research institute. The prominent functions are discussed in the rule 11 of the New Drugs and Clinical Trials Rules, 2019.

Functions of Ethics Committee

[14] Ministry of Health and Family Welfare**, "**New Drugs and Clinical Trials Rules, 2019, Rule 1(3)" (March, 2019).
[15] *Id.,* Rule 8.
[16] *Id.,* Rule 6.
[17] *Id.,* Rule 7.

Several functions lay down under the New Drugs and Clinical Trials Rules, 2019. The Ethics Committee for clinical trial shall perform the following functions for a person, institution or organization namely:

Duty to review and accord approval to a clinical trial*:* It is the duty of Ethics Committee to review and accord approval to a clinical trial, in the format specified in clause (B) of Table 1 of the Third Schedule and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.[18]

Duty to take review after interval*:* It is the duty to make at appropriate intervals, an ongoing review of the clinical trials for which it has accorded approval and such review may be based on periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.[19]

Duty to intimate for any changes in the protocol*:* Duty of Ethics Committee indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licensing Authority.[20]

Duty to inform in case of Serious Adverse Event: Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyze the relevant documents pertaining to such event and forward its report to the Central Licensing Authority.[21]

Duty to suspend clinical trial: Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the committee may order discontinuation or suspension of the clinical trial and the same shall be

[18] Ministry of Health and Family Welfare**, "**New Drugs and Clinical Trials Rules, 2019", Rule 11 (March, 2019).
[19]*Ibid.*
[20]*Ibid.*
[21] *Ibid.*

intimated to the head of the institution conducting clinical trial and the Central Licensing Authority.[22]

Duty to follow ethical guidelines and comply with guidelines: It is the duty of ethics committee to allow any officer authorized by the Central Licensing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects also to communicate the compliance with the approval of Central Government to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.[23]

After careful analysis of the functions, Ethics Committee has to play very major role in the clinical trial. Clinical Trial is a very complicated and lengthy process. Several different stages are involved in the process such as informed consent process, documentation, invasion of drugs in five kinds of clinical trials *etc*. Possibility of the misuse of the informed consent is very high at every stage. Independent body is to observe the application of an ethical guideline and rules neutrally at every stage to protect the interest of research participant. Therefore, observance of the ethical standard is the major responsibility imposed by the New Drugs and Clinical Trials Rules, 2019. In fact, the Ethics Committee is the protector and guarantor of the rights of the research participant. The prime duty of Ethics Committee is to observe the ethical standards and act independently and impartially to protect the interest of research participant.

IV. A critical analysis of the role and functions of the Ethics Committee

Good Clinical Practices Guidelines and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 has set the fundamental principles for the clinical trial.[24] Independency and Competency are the benchmark of Ethics Committee. It is expected that the Ethics Committee should function without any external force with its fullest capacity.

[22] *Id.,* at 20.
[23] *Ibid.*
[24] Dr. Roli Mathur, (eds.), *National Ethical Guidelines for Biomedical and Health Research involving Human Participants* 3 (Indian Council of Medical Research*,* New Delhi, 2017).

The major function of the EC is to review and accord approval to clinical trial and to observe the conduct of clinical trial. This committee has to ensure the safeguarding of the rights, safety and wellbeing of the research participant[25] with the rules and as described in Good Clinical Practices Guidelines. The basic responsibilities of the Ethics Committee is to ensure a competent review of all ethical aspects of the project proposals and implement the same from any bias and influence and to protect the dignity, rights and wellbeing of the potential research participant.[26] The objectives set under the Good Clinical Practices Guidelines are Principles of totality of responsibility and principles of accountability and transparency[27] can be achieved through the Ethics Committee constituted for the clinical trial.

In short, Ethics Committee is constituted to observe the protocols in the interest of the research participant. Express obligations are imposed upon the Ethics Committee to protect the rights, dignity and wellbeing of the research participant. This would be an ideal objective set in The New Drugs and Clinical Trials Rules, 2019 and GCP as well.

Formation of Ethics Committee *vis-a-vis* Concept of Independence

It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.[28] Seventy Second Report of the Parliamentary Standing Committee[29] on the "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India had emphasized that obtaining informed consent from study subjects is a fundamental requirement in the conduct of clinical trials to ensure that the human rights of the study subjects are ensured.[30] Also, Committee observed the serious violation of rights of research participant had

[25] *Supra* note 11 at 20.
[26] *Id.,* at 28.
[27] *Id.,* at 27.
[28] *Supra* note 6 at 1.
[29]In the course of Demand for Grants (2010-11), the issue pointed by the Department-related Parliamentary Standing Committee on Health and Family Welfare relating to the trial of Human Papilloma Virus (HPV) vaccine on the children in Khammam district of Andhra Pradesh and Vadodra district of Gujarat and reported deaths of the children. Accordingly, a Committee was appointed by the Government of India to enquire into" Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India on April 15, 2010.
[30] Parliamentary Standing Committee, "*72nd Report on Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine"* (Department-Related Parliamentary Standing Committee On Health And Family Welfare, 2013), *available at*:

taken place during the entire informed consent process.[31] Further, the Committee mentioned that the Ethics Committees existed only as a formality and they did not play the role they were designated for. This is a clear dereliction of duty on the part of the Ethics Committees and recommended the suitable mechanism for dereliction of Ethics Committee.[32] This incident would have been avoided at the initial state if Ethics Committee would have worked efficiently and fearlessly as expected by the law.

With this background, I argue that the power and duty to constitute Ethics Committee is imposed upon the Sponsor or the investigator or the applicant who intends to conduct clinical trial. It is very obvious and natural that known, identified, near and dear qualified members of Ethics Committee shall be appointed by the Sponsor or Investigator or the applicant. Present enforceable rules are totally silent for the procedure to select qualified Ethics Committee Member. Discretionary and arbitrary power is enjoyed by the Sponsor or Investigator or the applicant in the selection process which is against the recognized principle of law *i.e.,* Power should not be absolute. Lord Atcon quoted: "because power tends to corrupt and absolute power corrupts absolutely[33]" is relevant here.

After exercising the powers, appointed members for the Ethics Committee is presumed to be impartial and independent while discharging the duties.[34]. Independency and Competency are the virtues of the rules. The analysis of the notion of independence reveals two components:

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http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/72.pdf (last visited on Nov. 7, 2020).

[31] In para. 6.16, Committee noted the observations that for the uneducated subjects, the law requires an independent person to explain and witness the consent process. The Committee is however, deeply shocked to find that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms3944 have thumb impressions and 5454 either signed or carried thumb impressions of guardians. The data also revealed that a very large number of parents/guardians are illiterate and could not even write in their local languages *viz.* Telugu or Gujarati. The Committee is further shocked to find from one of the reports that out of 100 consent forms or Andhra Pradesh project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact the legality of Andhra Pradesh State Government directing headmasters in all private/Government/ashram/schools to sign the consent form on behalf of parents/guardians is highly questionable. The absence of photographs of parents/guardians/wardens on consent forms, the absence of signatures of investigators; the signatures of parents/guardians not matching with their names; the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms, etc. all speak of grave irregularities. (*available at:* http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/72.pdf) (last visited on Nov. 7, 2020)

[32] *Ibid.*

[33] Lord Acton, expressed this opinion in a letter to Bishop Mandell Creighton in 1887.

[34] *Supra* note 11 at 27.

authority and influence.[35] Independency of ethics committee means performing the obligations with an express authority without any influence directly or indirectly by the sponsor or investigator or applicant. If we analyze in this context, the combination of express or implied authority without any external or internal influence leads to the concept of independency. Together with this, Principles of transparency is the essential objectives for the ethical and safety consideration in the GCP. Clinical Trial will be conducted in a fair, honest, impartial and transparent manner. Then, a big question can be raised here that Ethics Committee being constituted by the Sponsor or Investigator or the applicant, may be able to act independently or impartially? The authority to constitute ethics committee is expressly granted by the New Drugs and Clinical Trials Rules, 2019 to the Sponsors, Investigators or any person who intends to conduct clinical trial. Whether such Ethics Committee may act independently or impartially in case of violation of protocol by the researcher against the sponsor or investigator or applicant?

Influence is another facet of the notion of independence which cannot be ignored in this discussion. Members being appointed by the Sponsor or Investigator are expected to perform their duties independently and impartially. Yet, the question may arise for the independency of the ethics committee and their functions. The power to constitute ethics committee and remove the members from the committee is entrusted with the Sponsor or the investigator or the applicant. With the fear to remove from the Ethics Committee, how any member may act against the sponsor? Also, there is high possibility for the presence of undue influence while discharging the duties by Ethics Committee. Is it possible for the Ethics Committee to give unfavorable decision against the Sponsors or Investigators or the applicant while exercising the power granted under the rules? Definitely, the answer would be in the negative form. Sponsor or Investigator or the applicant may use his superior position to create undue influence over the Ethics Committee. Good Clinical Practices Guidelines entrusted basic responsibilities upon the committee to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity.[36] The prominent issue is whether truly these obligations will be performed by ethics committee in its true spirit. Presence of the doctrine of bias in the functioning of the ethics committee cannot be

[35] Haftel, Yoram Z., and Alexander Thompson, "The Independence of International Organizations: Concept and Applications" 50 *The Journal of Conflict Resolution* 254 (2006).
[36] *Supra* note 11 at 28.

denied after the constitution of ethics committee. Possibility to misuse of power and act against the rights of the research participant cannot be denied because of the power to constitute and remove the members from the Ethics Committee. This is the major drawback that exists in the present rule and which is against the several ethical guidelines and principles of natural justice.

Absence of clear rules to select members to form Ethics Committee

The present rules are very vague in nature. Absolute powers are granted to the sponsor or investigator or the applicant to constitute Ethics Committee. No rules and regulations are mentioned regarding the selection of the members of the Ethics Committee. Also, there is no controlling machinery to verify the vested interest or any relationship of selected members with the sponsor or in the clinical trial. Rules expected that the members should be independent. The question is how and who is going to decide independency of the member? Rules are completely silent about it and there is no mechanism to identify the relationship between proposed member to be appointed in the ethics committee and sponsors, investigators, or the applicant. Present rules are not adequate enough to answer this question hence the laid down procedure to form ethics committee is not transparent and against the GCP and ICMR Guidelines. New Drugs and Clinical Trials Rules, 2019 deals with only power to constitute Ethics Committee and details about the composition of the Ethics Committee etc. But there is no express provision to decide the independence of the members and the procedure to select members for Ethics Committee. As Lord Atcon has rightly pointed out that, 'absolute power corrupts absolutely'. In this sense, such absolute power to constitute committee may be exercised arbitrarily. Lack of selection procedure and controlling mechanism in the selection procedure are the vital unaddressed issues reflected in the rules.

Report to the Central Licensing Authority in case of Serious Adverse Event

Discussion can be extended to study the other duties of ethics committee in the context of the protection of the rights of research participant. In case of any serious adverse event, Ethics Committee shall analyze the serious adverse event based on document and forward its report to the Central Licensing Authority.[37] Further, knowledge to the Ethics Committee about the

[37] *Id.,* at 20.

compromise the rights, safety and wellbeing of the trial, the committee may suspend or withdrawal the approval accorded to the Clinical Trial.[38] Ethics Committee being constituted by the Sponsor or Investigator or the applicant will submit report against appointing authority is a researchable question in this regard. Besides, even at any stage of clinical trial, for the violation or sacrifice of the rights or safety and wellbeing of research participant, ethics committee will take an appropriate action against sponsor or investigator or the applicant? Undoubtedly, such duty honestly will not be performed by the committee which will be against the rights of the research participant. Gross violation of right to research participant can be seen due to the passive role to be played by the Ethics Committee.

In short, Ethics Committee has to play a major role in the protection of the rights of the research participant during the clinical trial. The fundamental question may arise as discussed above in relevance with the independency and constitution of ethics committee. Is it justifiable and with the consonance of the natural justice that such committee may perform its duties genuinely and in the interest of research participant?

V. Conclusion

To apply the Latin maxim '*Primum non nocere'* (do not harm principle) in medicine, clinical trial should be conducted considering the safety measures and risk involved in it form the research participant's perspective. Now a days, it is an urgent need to introduce vaccine against the Covid-19. Despite this emergency situation, certain norms of clinical trial must be observed in the interest of the research participant. Nuremberg Code is the first document prepared at International Level to protect the interest of the research participant. Doctrine of Informed Consent, Doctrine of Self-determination, Compensation etc. fundamental principles has been evolved in this code. Later on, Helsinki Declaration, International Code of Medical Ethics, Belmont Report, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002 etc. ethical guidelines are published in relation to the clinical trial.

In India, ethical guidelines such as Good Clinical Practices Guidelines, 2002 and National Ethical Guidelines for Biomedical Research on Human Participants, 2017 are released by the

[38] *Ibid.*

CDSCO and ICMR respectively. Also, recently, New Drugs and Clinical Trials Rules, 2019 have been issued under the Drugs and Cosmetics Act, 1940 which contains the procedure to conduct clinical trial. Clinical trial is an essential step in the manufacturing of the safe and effective drugs. Drugs and Cosmetics Act, 1940 contains the provision for the manufacturing of the drugs. Numerous complex procedures are involved in the clinical trial. For this reason, ethics committee is suggested to supervise and monitor regular transactions in the clinical trial. The role and function of Ethics Committee is significantly highlighted in ethical guidelines at International level. Ethics Committee is required to observe the highest ethical standards while performing the various functions which are described at International Level in the Helsinki Declaration and International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002. Similarly, in India too ethical guidelines GCP and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 provides several provisions highlighting the significant role of the Ethics Committee.

New Drugs and Clinical Trials Rules, 2019 has provided several ideal functions of Ethics Committee in the interest of the research participant of the clinical trial. Independency and Transparency are the benchmarks to attain during the clinical trial. After analyzing carefully, the core concepts of the independent and selection of the members of the constitution in the Ethics Committee, it is found that the basic attributes of the concept of independency is not reflected in the rules as well as in the Good Clinical Practices Guidelines.

Constitution of Ethics Committee by the Governmental Authority

To achieve the goals set in the Good Clinical Practices through the Ethics Committee, certain reformation in the appointment of the members of Ethics Committee is essential. Authority and influence are the key aspects of the core concept of independency which can be achieved in different procedure of constitution of Ethics Committee. Authority and influence, the key features of the concept of independency, can be reflected if such committee is constituted by the Government *i.e.,* Drug Controller. The power to form Ethics Committee should be transferred with the Governmental Authority. Such Governmental Authority will appoint Ethics Committee for the clinical trial without any influence of the Sponsor, Investigator or the applicant, or any other person. Government constituted Ethics Committee will perform the obligations imposed

by the rules independently and impartially. Such committee in real sense will give justice to protect the rights, safety and wellbeing of the research participant. Without the influence and independently, such committee will function the described duties in the rules effectively and efficiently in the interest of the research participant. Attribution of the concept of independency will be reflected in this fair procedure. Authority and Influence will be clearly reflected in this procedure. Accordingly, principle of transparency can be achieved. The procedure to appoint independent ethics committee will be fair, transparent and honest. Chances of biasness will be null and the objectives set in the ethical guidelines and New Drugs and Clinical Trials Rules, 2019 can be attained.

Procedure to appoint members to Ethics Committee

Detailed rules of the qualification of the members should be incorporated in the New Drugs and Clinical Trials Rules, 2019 to avoid ambiguity and to maintain transparency in the rules. Researcher has suggested that the clinician having ten years medical practice experience in the proposed clinical trial related subject, can be appointed by the Governmental Authority. Government will prepare such area wise list accordingly. After receipt of application to conduct clinical trial, immediately, with the consent of such clinician, he can be appointed in the Ethics Committee. The same procedure can be adopted to appoint legal expert and other members as well. Such Ethics Committee is directly responsible and answerable to the Government. To avoid any kinds of biasness, this change will be effective and remove the doubts of being misused by the sponsors or investigators or the applicant. Further, procedure to appoint by the Government will be fair, honest and unbiased.

Absolute liability to forward report to the Government in case of serious adverse event

Absolute liability should be imposed upon the Ethics Committee to forward report to the appointing authority *i.e.,* government in case of serious adverse event happens during clinical trial or in case of violation of any of the rights of research participant during the clinical trial. Non observance of the duty may attract heavy finds against the members of the Ethics Committee. Merely, suspension of the membership or Ethics Committee is not enough.

Stringent provision should be incorporated in the current rules to give justice to the research participant.

In nutshell, to resolve the above discussed issues, Ethics Committee should be formed by the Government to avoid undue influence and to maintain the impartially in the procedure to constitute Ethics Committee. Such procedure will be fair and just in the eyes of law. Such government appointed Ethics Committee may give proper justice to the research participant while performing the functions laid down under the New Drugs and Clinical Trials Rules, 2019. In true sense, rights of the research participant can be protected and enforced through this provision. Qualification to appoint members and procedure to appoint member required to be modified in the interest of the research participant as discussed above. The objectives of Good Clinical Practices Guidelines are Independency, Impartiality and Transparency can be achieved through the amendment in the New Drugs and Clinical Trials Rules, 2019.