

## WHETHER FUNDAMENTAL RIGHT TO HEALTH SUBSISTS AFTER THE PARTICIPATION BY HEALTHY RESEARCH PARTICIPANT IN CLINICAL TRIALS?

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**ABSTRACT:** *Health is one of the most important factors for the survival of a human being. Healthy members in the society act as the reflection of the existence of how developed the country is. The healthier the population the better the chances and the developed the country is. Due to the increasing concern about health the researchers are trying to study the concept of fundamental rights under article 21 of Constitution of India. For improvement in the Health Care facilities there is a need that the research are conducted on the human beings for advancing the medical and scientific knowledge. Humans being an essential part of the clinical trial, several rights of the research participants are recognized under the Indian Constitution, New Drugs and Clinical Trials Rules, 2019 and The Drugs and Cosmetics Act, 1940. The beneficiaries to the fundamental right to health are all persons including research participant of the clinical trial. After getting recruited in the clinical trial, anticipated serious adverse reactions are like must to happen or bound to happen on healthy research participant which directly affects his health and the body. Each clinical trial involves extreme risks and possibilities of harm to the research participant or the host. For the purpose of the clinical trials the jurisprudential base needs to be also taken into consideration. The part III part IV of the Constitution of India provides directive principles.*

**KEYWORDS:** *Clinical trials, health, human being, fundamental rights, right to health.*

### A. INTRODUCTION

Supreme Court of India has acknowledged the significance of right to health and quoted that the “maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends on the building of the society of which the constitution makers envisaged.

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Attending to public health, in our opinion, therefore, is of high priority—perhaps the one at the top”.<sup>1</sup>*Vincent v. Union of India*, AIR 1987 SC 990: (1987) 2 SCC 165.

Right to health is the major concern of every country. Healthy members of the society are the reflection of the existence of the developed country. The responsibility lies to protect, preserve and respect the right to health upon the State and Medical Professionals. It is the obligation of the State to create and maintain healthy atmosphere for the welfare of the society and to promote medical professionals to extend efforts to prevention and cure the disease.

The Researcher seeks to study the concept of fundamental right to health under article 21 of the Indian Constitution. Right to health can be enjoyed through advanced medicine. Without the clinical trial, medicine cannot be developed. Research on human being is essential for the improvement in medical and scientific knowledge. Being an essential part of the clinical trial, several rights of the research participants are recognized under the Indian Constitution, New Drugs and Clinical Trials Rules, 2019 and The Drugs and Cosmetics Act, 1940. The fundamental right to health is extended to the research participant of the clinical trial. Every Clinical trial has some inherent risks involved in it which directly affects the right to health of the research participant. Participation in clinical trial involves several issues such as fundamental right to health of research participant, waiver of fundamental right, role of the law in welfare state etc. Researcher attempts to address this issue in this research paper.

## **B. RIGHT TO HEALTH AT INTERNATIONAL LEVEL**

Health is a global, national and individual concern and the subject of intensive international cooperation, coordinated in particular by the WHO.<sup>2</sup> The preamble of the constitution of the WHO states that ‘the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition’, and adds that ‘healthy development of the child is of basic importance; the ability to live harmoniously in a changing total

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<sup>1</sup> *Vincent v. Union of India*, AIR 1987 SC 990: (1987) 2 SCC 165.

<sup>2</sup> The World Health Organization is specialized agency of the United Nations related with the world public health. The responsibilities of WHO are World Health Report, The Worldwide World Health Survey and World Health Day.

environment is essential to such development'.<sup>3</sup>The World Health Organization defines the right to health as "a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity."<sup>4</sup>WHO definition covers the significant and inescapable role of clinical trial towards the maintenance of physical, mental and social wellbeing. States should ensure both freedoms and entitlements. The former include the right to control one's health and body, including sexual and reproductive freedom, and the freedom from interference such as torture, non-consensual medical treatment and experimentation. Entitlements include access to adequate health care facilities and services, as well as appropriate State measures in relation to the socio-economic determinants of health, such as food, water and sanitation, safe and health working conditions, housing, and poverty.<sup>5</sup>

As a core concern in modern human rights, the right to health is recognized in numerous international instruments.<sup>6</sup> Universal Declaration of Human Rights affirms that 'Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services'.<sup>7</sup> State Parties recognize 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' and enumerates 'steps to be taken by the States parties to achieve the full realization of this right'.<sup>8</sup> The right to health is also recognized, inter alia, in Article 5 (e)(iv) of the CERD<sup>9</sup>, and in Articles 11 (1)(f) and 12 of the CEDAW.<sup>10</sup> Paramount significance has been conferred to the right to health of every person including research participant in clinical trial at International level.

<sup>3</sup> VandeLanotte, E. Verhellen, F. Ang, E. Berghmans and M. Verheyde (eds.), *A Commentary on the United Nations Convention on the Rights of the child*, 1 (Leiden: Martinus Nijhoff Publishers, 2006).

<sup>4</sup> <https://www.escr-net.org/rights/health> (Last visited on 25th Feb., 2020).

<sup>5</sup> <https://www.escr-net.org/rights/health> (Last visited on 25th Feb., 2020)

<sup>6</sup> VandeLanotte, E. Verhellen, F. Ang, E. Berghmans and M. Verheyde (Eds.), *A Commentary on the United Nations Convention on the Rights of the child*, 1 (Leiden: Martinus Nijhoff Publishers, 2006).

<sup>7</sup> Universal Declaration of Human Rights, 1948, article 25 (1).

<sup>8</sup> Convention on Economic and Social Cultural Rights, 1966, article 12.

<sup>9</sup> Convention on the Elimination of All Forms of Racial Discrimination, 1965.

<sup>10</sup> Convention on the Elimination of All Forms of Discrimination against Women New York, 18 December 1979

### **C. CONSTITUTIONAL ASPECT OF RIGHT TO HEALTH**

The Constitution is the supreme law of the land. The Constitution of India guarantees the fundamental rights under Part III. Part IV of the Indian Constitution contains the Directive Principles of State Policy. The Preamble reflects the objectives to be achieved through the Constitutional framework. Duty is imposed upon the State to fulfill the objectives. The Preamble directs the state to initiate measures to establish justice, equality, ensure dignity, etc. which have a direct bearing on people's health.<sup>11</sup> The right to live with human dignity and the same does not connote continued drudgery. It takes within fold some of the fine graces of civilization which makes life worth living and that the expanded concept of life would mean the tradition, culture and heritage of the person concerned".<sup>12</sup> The right to live with dignity encompasses right to health under Art. 21 of Indian Constitution. The right to health has been well recognized by the Supreme Court under Article 21<sup>13</sup> of Indian Constitution. The right to health has numerous facets discussed by the Apex Court. Justice Bhagwati has observed that the "the right to life includes the right to live with human dignity and all those goes along with it, namely, the bare necessities of life such as adequate nutrition, clothing and shelter over the head and facilities for reading, writing and expressing oneself in diverse forms, freely moving about and mixing and commingling with fellow human beings".<sup>14</sup> Further, in the landmark judgment of '*Vincent Panikurlangara v/s Union of India*', Supreme Court has held that in a welfare state, it is the obligation of the State to ensure the creation and maintaining of conditions congenial to good health. The right to enjoy life as a serene experience, in quality far more than animal existence is thus recognized. Personal autonomy, free from intrusion and appropriation is, thus a constitutional reality. The right to live in peace, to sleep in peace and the right to repose and health are part of the right to live.<sup>15</sup>

In *CESC Ltd. v/s. Subash C. Bose*<sup>16</sup>, Apex court held that the right to health is a fundamental right and further elaborated that the "The term health implies more than an

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<sup>11</sup> N. B. Sarojini & others, *Women's Right to Health*, 85 (New Delhi: National Human Rights Commission, 2006).

<sup>12</sup> *P. Rathinam v. Union of India*, (1994) 3 SCC 394.

<sup>13</sup> Constitution of India. Art. 21 – "No person shall be deprived of his life and personal liberty except according to the procedure established by law."

<sup>14</sup> *Francis Coralie v. Delhi*, AIR 1981 SC 746.

<sup>15</sup> 1987 AIR (SC) 990.

<sup>16</sup> 1992 AIR (SC) 573, 585.

absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable manpower for economic development. Facilities of health and medical care generate devotion and dedication to give the workers' best, physically as well as mentally, in productivity. It enables the worker to enjoy the fruit of his labor, to keep him physically fit and mentally alert for leading a successful economic, social and cultural life. The medical facilities are, therefore, part of social security and like gilt edged security, it would yield immediate return in the increased production or at any rate reduce absenteeism on grounds of sickness, etc. Health is thus a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

It was in 1995 in the case of *Consumer Education and Research Centre v/s. Union of India*<sup>17</sup>, that the Supreme Court for the first time explicitly held that 'the right to health is an integral part of a meaningful right to life.' This case was concerning the occupational health hazards faced by workers in the industry. Reading Article 21 with the relevant directive principles guaranteed in articles 39(e), 41 and 43 of the Indian Constitution, the Supreme Court held that the right to health and medical care is a fundamental right and it makes the life of the workman meaningful and purposeful with the dignity of person. This recognition established a framework for addressing health concerns within the area of public interest litigation and in a series of subsequent cases, the Court held that it is the obligation of the State not only to provide emergency medical services but also to ensure the creation of conditions necessary for good health, including provisions for basic curative and preventive health services and the assurance of healthy living and working conditions.

Directive Principles of State Policy contains several provisions related with the right to health though the Directive Principles of State Policy is not enforceable in nature. Article 39

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<sup>17</sup> 1995 AIR 922, 1995 SCC (3), 42 JT 1995 (1) 636, 1995 SCALE (1)354.

(e)<sup>18</sup> and (f)<sup>19</sup>, 41<sup>20</sup> and 42<sup>21</sup> and 43<sup>22</sup> are observed the relevance of right to health to all. State is obligatory to provide atmosphere which enable the person to enjoy the right to health and to maintain the dignity of human life. The court has ruled that the Constitution envisages establishment of a welfare state, and in a welfare state, the primary duty of the government is to provide adequate medical facilities to the people. The government discharges this obligation by running hospitals and health centers to provide medical care to the needy person.

To be precise, fundamental right to health is applicable to research participant of clinical trial. Supreme Court of India broadly reconnoitered Art. 21 of Constitution in various judicial pronouncements and extended benefits of right to health as fundamental right of every person including research participant of the clinical trial. Further, the concept of 'welfare state' can be visualized through the healthy people of the state and government is duty bound to maintain and provide the medical health services to the people at large. It is the constitutional mandate of the state described in Directive Principles of State Policy to provide necessary medical facilities and advanced medicine to cure the diseases.

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<sup>18</sup> Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing-(e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;

<sup>19</sup> Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing-(f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.

<sup>20</sup> Right to work, to education and to public assistance in certain cases: The State shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want.

<sup>21</sup> 42. Provision for just and humane conditions of work and maternity relief The State shall make provision for securing just and humane conditions of work and for maternity relief.

<sup>22</sup> Living wage, etc, for workers The State shall endeavor to secure, by suitable legislation or economic organization or in any other way, to all workers, agricultural, industrial or otherwise, work, a living wage, conditions of work ensuring a decent standard of life and full enjoyment of leisure and social and cultural opportunities and, in particular, the State shall endeavor to promote cottage industries on an individual or co operative basis in rural areas.

#### D. JURISPRUDENTIAL BASE TO RIGHT TO HEALTH OF RESEARCH PARTICIPANT IN CLINICAL TRIAL

Even jurisprudentially, the two main ethical theories provide different answers to medical research. From a duty based (or deontological) approach, the researcher would owe a duty to the research subject not to harm them in carrying out the research. The duty is not to sacrifice one individual for the sake of others. This raises the dilemma that an individual research subject should not be used as a means to an end, that of greater medical knowledge. A duty based approach also gives the research subject the right to have their autonomy respected.<sup>23</sup>

#### E. NECESSITY AND DEFINITION OF CLINICAL TRIALS

Suffering from different diseases is the inevitable part of the human life. Prevention from disease and cure the disease with the effective drug are the probable solution to address this issue. Every human being should be entitled to get safe, quality and effective drugs against the disease. The purpose of drug is to preserve the health of the people and ultimately the nation. Availability of effective and quality drugs is the prerequisite to fulfill the obligations of the state. Clinical Trial is an indispensable step to manufacture safe and quality drugs regulated under the Drugs and Cosmetics Act, 1940 which is an integral part of right to health. Recently, New Drugs and Clinical Trials Rules, 2019 has been introduced to regulate clinical trial. 'Clinical Trial' means a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-

- (i) clinical or;
- (ii) pharmacological including pharmacodynamics, pharmacokinetics or;
- (iii) adverse effects,

with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.<sup>24</sup> Thus, it is crystal clear that the object of the clinical trial is to determine the safety and effectiveness of new drugs. But there is a difference between 'medical research and experimentation'. 'Therapeutic and Non-therapeutic research' is the two categories of the research. Therapeutic research is aimed at helping an individual patient

<sup>23</sup> Brendan Greene, *Understanding Medical Law*, 155-156, (London: Cavendish Publishing Limited, 1<sup>st</sup> Publication, 2005).

<sup>24</sup> New Drugs and Clinical Trials Rules, 2019. Pg. 148.

or group of patients; non-therapeutic research is carried out on patients but is unlikely to be of benefit to them directly, although the aim of the research is to increase knowledge generally. Research may also be divided into non-invasive and invasive. With non-invasive research, the research subject is not given any treatment but, for example, their medical history is used as part of a research project. With invasive research, the research subject is given drugs or a medical procedure is carried out on their body and this creates a risk.<sup>25</sup> Therefore, patient and healthy research participation can be admitted in the clinical trial. Patient and healthy research participation are entitled to enjoy fundamental right to health. However, Legal issue in respect of fundamental right to health of healthy research participant after admission voluntarily in the clinical trial and waiver of fundamental right to health of the research participant raises serious concern discussed below.

#### **F. FUNDAMENTAL RIGHT TO HEALTH OF RESEARCH PARTICIPANT IN CLINICAL TRIAL VIA-A-VIS-WAIVER OF FUNDAMENTAL RIGHT BY PARTICIPATION IN THE CLINICAL TRIAL**

It is widely accepted fact that clinical trial is an inevitable part of the modern medicine for the advancement of medicine. Right to health is worthless unless advanced medicine is being made available to cure the disease. Clinical Trial becomes inevitable for the advancement of medicine and knowledge. Participation of healthy research participant is the necessity of the clinical trial. Beneficiaries of fundamental right to health are all persons including research participant of the clinical trial. After the admission in the clinical trial, anticipated serious adverse reactions are bound to happen on healthy research participant which directly affects his body. Every clinical trial involves inherent risks and possibilities of harm to the research participant. Question for the discussion here is the violation of fundamental right to health of healthy research participant in case of non-therapeutic research and waiver of fundamental right to health by healthy research participant.

1) Object of International & National Ethical Guidelines for Biomedical Research involving Human Participants :

Respect for Autonomy, Non-maleficence (first do not harm), Beneficence and Justice are the key ethical principles described in the International and National Ethical Guidelines for Biomedical Research involving Human Participants. These guidelines has laid down the objectives, standards and procedure to be followed while conducting clinical trial. The purpose is to protect the healthy research participant's right and extend benefits to the

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<sup>25</sup> *Supra* note 23 at 155.

patients or society at large. Accordingly, Good Clinical Practice Guidelines has been issued by the CDSCO<sup>26</sup>. Good Clinical Practice Guidelines 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. The fundamental tenet of Good Clinical Practices is that in research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the study subject. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated.<sup>27</sup> The International & National Ethical Guidelines for Biomedical Research involving Human Participants are aimed to protect the rights of the research participant and laid down several safeguards and procedure to prevent the violation of rights of research participant. The healthy research participant can be admitted with his voluntary consent. The guidelines has not considered the valid reason behind the voluntary participation by healthy person in the clinical trial. This is the major reason behind the ignorance of incorporation of the provisions in the local statutes or polices, i.e. Statement of reasons behind participation in the clinical trial.

2) Analysis of the reasons behind clinical trial participation by healthy participant:

The participation by healthy research participant in clinical trial for non-therapeutic purpose invites several legal issues. Most of the time, healthy research participant is voluntarily admitted for obvious reasons such as monetary issue, illiteracy, lack of education, lack of awareness about trial, fraud etc. Without these reasons, for non-therapeutic purpose, how and why healthy research participant would admit himself for the clinical trial. The central apprehension is after the knowledge of the risk and losses involved in the clinical trial and after understanding the nature of the clinical trial, any ordinary or reasonable person would participate voluntarily in the clinical trial and expose himself for the loss and risk to the body. Voluntariness means agree to take part in clinical trial after the detailed understanding of nature of the clinical trial, the pros and cons of the participation, risk to his body, probable consequences upon his health etc. Generally, without the monetary justification, nobody will

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<sup>26</sup> Central Drugs Standard Control Organization formulated guidelines to conduct clinical trial called Good Clinical Practice Guidelines.

<sup>27</sup> Good Clinical Practice Guidelines, Pg. 1

be ready to be a part of clinical trial and accept the inherent risk involved in the clinical trial to the life or body of research participant. Assuming these reasons behind the participation of the healthy research participant in clinical trial, it is the biggest failure of the state which compels or forces healthy research participant indirectly to participate in the clinical trial.

3) Relevancy of Role and object of the State and Clinical Trial:

'Welfare state' is the constitutional mandate of the state and elaborated by the Supreme Court in '*Paschim Banga Khet Mazdoor Samity v. State of West Bengal*'.<sup>28</sup> 'The Constitution envisages the establishment of a welfare state at the federal level as well as the State level. Welfare State is regarded as a system wherein a minimum social responsibility for certain minimum standards of individual and communal welfare set. Also, Justice, Liberty, Republic, Democracy etc are the essentials of welfare state. Democratic republic fulfills the needs of society by turning its legislative process to regulate socio-economic matters, it is also known as the welfare state- a state that strives to secure the welfare of the people by establishing the essential conditions of good living.'<sup>29</sup> Essential conditions are identified as the improvement of the conditions of life physically, mentally, emotionally, economically and politically of socially handicapped individuals or otherwise disadvantaged individuals or groups.<sup>30</sup> In a welfare state the primary duty of the Government is to secure the welfare of the people'. This social welfare can be achieved through economic justice as well. As explained in the case of '*CERC v. UOI*', that the social justice, right to economic justice, right to economic quality, economic empowerment of the weaker section of the society constitute Fundamental Rights. The aim of social justice is to attain substantial degree of social, economic and political equality. Social justice and equality are complementary to each other.<sup>31</sup> Also, right to health and social justice has been held to be a Fundamental Right of the worker. The Supreme Court has derived this right by reading Article 21 with Articles 39(e), 41, 43 and 48A.<sup>32</sup>

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<sup>28</sup> (1996)4 SCC37.

<sup>29</sup> [https://shodhganga.inflibnet.ac.in/bitstream/10603/129421/9/09\\_chapter%204.pdf](https://shodhganga.inflibnet.ac.in/bitstream/10603/129421/9/09_chapter%204.pdf) Pg. 96

<sup>30</sup> [https://shodhganga.inflibnet.ac.in/bitstream/10603/129421/9/09\\_chapter%204.pdf](https://shodhganga.inflibnet.ac.in/bitstream/10603/129421/9/09_chapter%204.pdf)

<sup>31</sup> AIR 1995 SC922.

<sup>32</sup> *Consumer Education Research Center v. Union of India*, AIR 1995 SC 922.

Consequently, achievement of social and economic justice is possible when substantial opportunities are created in the state and people are exercising their right to get employment. But, unfortunately, this ideal and welfare state has not yet formed. It is the biggest failure of the state. Due to the failure of the state to establish 'welfare state', research participant has to admit in the clinical trial for monetary gain. With this relevance, failure of the state to create suitable employability, compels the people to join the clinical trial against their will but due to economic reasons. To gain some amount, people prefer to be a part of the clinical trial. It is the biggest failure of the state to provide employment to every person or set up societal structure in such manner that every person would be educated, employed or economically sound.

#### 4) Legality of Consent as a defense to the researcher:

Law has accepted the value of consent and well recognized as a good defense even in clinical trial too. '*Volenti Non Fit Injuria*' is well recognized defense in civil law. Harm suffered voluntarily does not constitute a legal injury and is not actionable. The principle is embodied in the maxim *volenti non fit injuria* (where the sufferer is willing no injury is done). The maxim *volenti non fit injuria* is founded on 'good sense and justice'.<sup>33</sup> In *Samira Kohli v. Prabha Manchanda*<sup>34</sup> case, Supreme Court laid down the law on the question of consent which means that: the patient should have the capacity and competence to consent; his consent should be voluntary and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what he is concerning to.

Further, analyzing the defense of consent in regards to the participation of clinical trial has not considered the necessity and object behind the participation. Consent encompasses four components i.e. Competency of the research participant, adequate information of the subject matter, understanding of the subject matter and voluntariness. Research participant is expected to give consent after the observations of all essentials and steps of the consent. Broadly speaking, obtaining consent from a research participant authorizes a clinician or researcher to have physical contact with the participant. It also protects the rights of participants to exercise their own autonomy and retain control over what happens to them.<sup>35</sup>

<sup>33</sup> Ratanlal & Dhirajlal, *The Law of Torts*, 94, LexisNexis Publication: Gurgaon, 28<sup>th</sup> Edition, 2018.

<sup>34</sup> (2008)2 SCC 1.

<sup>35</sup> Hazel Biggs, *Healthcare Research Ethics and Law*, 78, (Routledge Cavendish: Oxon, 1<sup>st</sup> Publication, 2010).

Therefore, consent is the form to seek authority for the intervention of physical integrity of the body, personal data etc. Unauthorized interference with the bodily integrity or liberty of a person is regarded as trespass. It is based on the premise that people have the right to individual autonomy, which should be respected by others.<sup>36</sup>

Consent is widely accepted defense but the reasons behind the giving voluntary consent has not been considered by law. Whereas, the Restatement of Torts tersely states in this regard that “consent is not effective if it is given under duress”. Alan Wertheimer notes that inducement, persuasion and authority are all forms of pressure that may be considered coercive in certain circumstances and threat is one form of coercive which ultimately restricts the choices of the individual options.<sup>37</sup> In short, consent is valid when it is given without coercion which inherently includes ‘analysis of reason behind participation for money or life’. In the Informed Consent of clinical trial, ‘reason behind participation in clinical trial’ should be assimilated. Consent is obtained due to offering money to healthy research participant is a coercion which affects the right to autonomy and validity of consent. But presently, New Drugs and Clinical Trials Rules, 2019 has not ignored this aspect and anticipated only free, informed and written consent from the research participant.<sup>38</sup> Under the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, comprehensive Informed Consent Process is laid down. A guideline 5.1.2 declares that the consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements. In spite of this, unfortunately, the voluntarily consent does not cover ‘reasons behind participation’ which ultimately leads to the invalid consent of the research participant for the clinical trial. Being ‘Invalid Consent’ is no more a good defense in law which ultimately results into waiver of fundamental right to health of research participant.

#### 5) Applicability of the Doctrine of Waiver in clinical trial:

Right to health is recognized as a fundamental right under article 21 of Indian Constitution. Hence, fundamental right to health is always enjoyed by the research participant in clinical trial as well. This informed consent if vitiated due to duress as discussed earlier becomes

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<sup>36</sup> *Ibid.*

<sup>37</sup> Appelbaum, Paul S., Berg, Jessica W., and Lidz, Charles W., *Informed Consent : Legal Theory and Clinical Practice*, 67-68 (Oxford University Press, USA, 2nd Edition, 2001).

<sup>38</sup> New Drugs and Clinical Trials Rules, 2019, Third Schedule. Pg. 210.

'invalid consent' and ultimately gives scope for the violation of fundamental right to health. Therefore, research participant is giving up his right to health and accepts the risks involved in the clinical trial voluntarily. Therefore, the fundamental right to health guaranteed by the Article 21 of Indian Constitution to the research participant has waived up expressly and impliedly through participation in the clinical trial even though with the consent given by research participant. In the case of *BaseshwarNath v. IT Commissioner*<sup>39</sup> Supreme Court expounded several views regarding waiver of Fundamental Rights. viz:

i) No person can, therefore, by any act or conduct relieve the state of the solemn obligation imposed on it.

ii) Fundamental rights cannot be waived by a person. The Fundamental Rights are mandatory on the state and no citizen can by his act or conduct relieve the state of the solemn obligation imposed on it. Here, healthy research participant through participation voluntarily give up the fundamental right to health is actually a serious concern. It would be a constitutional unfairness.

iii) Also, the minority judges took the view that an individual could waive a Fundamental Right which was for his benefit but he could not waive a Right which was for the benefit of the general public which was not accepted.<sup>40</sup> Justifications were added that the large majority of the people in India are economically poor, educationally backward and politically not yet conscious of their rights by the Supreme Court in this case.

To conclude, I would say that the healthy research participant should not be admitted in the clinical trial otherwise it would violate the healthy research participant's right to health as enshrined in the Indian Constitution under Article 21. It is the failure of the state which forces indirectly to the research participant to join clinical trial. Therefore, right to health as a fundamental right is waived up by the research participant in the process of clinical trial.

## G. CONCLUSION AND RECOMMENDATIONS

Right to health is acknowledged as fundamental right under article 21 of the Indian Constitution. Right to health means right to be physically and mentally fit. Concept of health would be incomplete if appropriate and effective medicines are not provided to the patient. Right to health would be insignificant unless quality drugs are provided to them. Clinical trial

<sup>39</sup> AIR 1959 SC 149.

<sup>40</sup> *BaseshwarNath v. IT Commissioner* AIR 1959 SC 149.

is an essential step for the manufacturing of quality drugs. The object of clinical trial is to get knowledge and to find out the better methods to prevent, diagnosis and therapy which will be beneficial to the community at large. To achieve this object, human participation in the clinical trial becomes inevitable.

Participation of human being is essential in many of the clinical trial and accordingly fundamental right to health benefitted to the research participant is in dispute. Healthy research participant joins the clinical trial for economical gain or because of illiteracy or non education or even fraud as well. Voluntary Consent is a legal authority given to sponsor or investigator to conduct clinical trial upon healthy research participant. Concept of consent has not considered the reason behind voluntary consent. Voluntary consent should contain the identification and analysis of the reason in the rules. Monetary gain, illiteracy or non education should not be the reasons behind voluntary consent. With this reason, given consent becomes legally invalid due to the presence of 'duress or coercion' in the informed consent process. Therefore, informed consent cannot be a legally valid defense for the violation of research participant's fundamental right to health.

Because of essentiality of healthy research participant in the clinical trial, object or reason behind participation in clinical trial should be the given enormous significance in the informed consent process. The object to help to society is a noble, ideal and valid reason for the participation in clinical trial. It is considered as a precious social value. Hence, voluntary consent with this reason would be the valid reason for the participation. The meaning of voluntariness gets fulfilled with this justification.

In addition to this, if state has made competent person for the employment and well educated, healthy person naturally would not turn to be a part of clinical trial for monetary gain and naturally his fundamental right to health would not be question. In a welfare state, state could achieve social and economic justice in true sense, failure of the state and compulsion to participate for economic gain would not be discussed as well. Employability, Education to all and awareness about the informed consent process and the contents of it and inculcation of social values are the preventive and remedial measures to resolve the issue and the object of law to promote clinical trial with the protection of the rights of research participant can be achieved in true sense.

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