CHAPTER II
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2.1 Need for the study:

The need for the study arose out of many factors. The altruistic motive, courage of a naive research subject to participate in a preventive HIV vaccine clinical trial which may not benefit him personally and his willingness to face the risks as well as associated non-medical social harms ranks first. The dedication of the researchers and stake holders to work towards a preventive vaccine which can save the mankind despite all hurdles ranks next. The participants and researchers are both perplexed with the problems related to existing lacunae in the legislation which may not address the ethical dilemmas involved in a preventive HIV vaccine trial which in turn force them to face severe challenges.

2.2 Statement of Problem:

The whole study is aimed at addressing the lacunae in the existing legal frame work in addressing the ethical issues arising out of HIV vaccine clinical trials in India. India was considered a hub of clinical trials a couple of years back. Due to weak regulatory scenario and a myriad of other contributory factors, human experimentation in India was considered rash and risky. HIV is a deadly virus which can evade the immune system surveillance and tamper the immune system, the very system responsible for protecting human beings against diseases. HIV is unique in many ways and this make HIV vaccine clinical trial different from other clinical trials. Since many of the ethical guidelines and laws for human experimentation were formulated before the HIV pandemic, they fail to address the unique set of problems faced by researchers and the subjects in vaccine trials of HIV. Thus we need to modify the existing regulatory framework in order to address these issues effectively. Though the latest Supreme Court directives and amendment in Drugs and Cosmetic Act has brought in some light
of hope in the tunnel, much more is required to avoid harm of those who participate in these trials for a better tomorrow.

In this backdrop, the instant study “Legal and Ethical Issues of HIV Vaccine Clinical Trials in India- A Critical Study” intends to critically explore the legal and ethical issues related to preventive HIV vaccine clinical trials in India. The research analyses the adequacy of International and Indian regulatory instruments in addressing the issues unique to preventive HIV vaccine clinical trials. It further examines the limitations and suggests measures to improve the current grim scenario.

2.3 Objectives: The study is aimed at achieving the following objectives.

1. To understand clinical trials.
2. To explore clinical trial scenario in India.
3. To examine HIV vaccine clinical trials.
4. To appreciate the uniqueness of HIV.
5. To establish that HIV vaccine clinical trials are different from other clinical trials.
6. To assess the specific concerns related to HIV vaccine clinical trials, more so the ethical issues.
7. To examine the legal framework regulating clinical trials globally.
8. To evaluate the legal framework regulating clinical trials in India.
9. To critique the lacunae in the existing legal frame work in addressing the ethical issues arising out of HIV vaccine clinical trials in India.
10. To suggest, by way of conclusion, the various changes that may be brought out in the existing legal frame work in India to address the ethical issues in HIV vaccine clinical trials.

2.4 Research Hypothesis:

The researcher commences the study with a null hypothesis: The existing legal frame work in India is not adequate in addressing the ethical issues arising out of HIV vaccine clinical trials. The researcher endeavors to test the hypothesis.
2.5 Limitations of the study:

1. The study confines its scope and coverage to legal & ethical issues related to preventive HIV vaccine clinical trials conducted on adults males in India only.

2. Since the issues of a subject in preventive HIV vaccine trials are different from that in a therapeutic HIV vaccine trial, the researcher has only addressed those of Preventive HIV vaccine trials.

3. Due to the perplexity of the issues related to HIV vaccine trials in women, adolescents and children, the research undertaken is limited to the legal and ethical issues of adult male HIV vaccine clinical trial participants only.

4. The regulatory frame work pertaining to clinical trials in USA & EU are only examined, besides various international treaties and conventions related to clinical trials which are not legally binding.

5. Due to the confidential nature of the subject under study, the data related to ongoing projects are unavailable.

6. Further, due to aforesaid reason, interview with any trial participants could not be conducted, which otherwise would have validated the findings.

7. The researcher intends to examine all the ethical issues unique to HIV vaccine clinical trials in a nutshell. No attempt is taken to elaborate on any of these issues as each issue is exhaustive and is beyond the scope of this study.

8. Given the confidential nature of the topic under study, there were severe challenges for collating valid and reliable data related to the trial participants, apart from what is available in public domain, ie; Clinical Trial Registry India (CTRI).

2.6 Methodology:

The methodology adopted in this research study has been descriptive, comparative & analytical in nature. To understand clinical trials, to appreciate the uniqueness of HIV & to establish that HIV vaccine clinical trials are different from other clinical trials, descriptive method was used. The researcher adopted
comparative method to assess the specific concerns related to HIV vaccine clinical trials, more so the ethical issues, to analyze the legal framework regulating clinical trials globally & to evaluate the adequacy of the legal framework regulating clinical trials in India. Further analytical approach was resorted to critique the lacunae in the existing legal frame work in addressing the ethical issues arising out of HIV vaccine clinical trials in India and to suggest policy reforms.

Data was collected by reviewing existing literature from both primary and secondary sources. The primary sources referred for the study includes The Drugs and Cosmetic Act, national legislations, international treaties & guidelines pertaining to clinical trials, text books on HIV and vaccine science. Material collection was primarily from libraries of NLSIU Bangalore, PGIMER Chandigarh & AFMC Pune. Internet databases like Lexis Nexis, Manupatra, WestLaw International and Jstor were relied in collection of data. UNAIDS, World Bank & WHO documents on HIV /AIDS also proved helpful. Besides these, press release of relevance was also depended. Efforts were undertaken to reach eminent scientists in the field of HIV vaccine clinical trials, ethicists and investigative medical journalists.

Informal interactive interviewer method was adopted in interacting with the senior scientists at NARI who are instrumental in carrying out first ever HIV vaccine research in India. Questionnaire- cum – opinionnaire was prepared and sent to Director, NARI. Further, RTI was sent to NARI, CDSCO, Institute of Epidemiology but nothing was contributory. The purpose of this whole drill was to pinpoint the issues related to HIV vaccine clinical trials in the country, both from the technical point of view and regulatory. E mails were sent to Dr Sanjay Mehendale, Principal Investigator of the first HIV vaccine clinical trial in India & Director Indian Institute of Epidemiology, Ms Sandhya Srinivasan, eminent investigative medical and ethical journalist, Dr Amar Jesani, editor Indian Journal of Medical Ethics, Mr RajatGoyal , Vice President International AIDS Vaccine Initiative (IAVI).