CHAPTER I

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1.1 EXECUTIVE SUMMARY:

Human experimentation involves one of the most complex phases in the approval of any new drug entity. Over more than three decades, the world has been eagerly awaiting a preventive vaccine for HIV. Though there were efforts from the scientific community towards achieving this goal, there were many hurdles and we have not yet reached a stage where a vaccine is available with reasonable efficacy.

AIDS is one of the most complex, incurable and dreaded disease which is mostly attributable to the unique nature of the virus. Preventive HIV vaccine trials require healthy adults not affected with HIV. The complexities of HIV vaccine trials expose a subject to enormous risks and pose many ethical dilemmas for the subjects, researchers and other stakeholders.

Around the world, many countries do not even have regulations addressing the problems of People Living With HIV/AIDS (PLHA). The current regulatory scenario needs to be thoroughly examined as to what extent it addresses the ethical issues arising out of HIV vaccine clinical trials.

(a) Chapterization : The thesis is developed in seven chapters. The introductory chapter gives the brief executive summary of the entire thesis.

The second chapter titled “The Research Study and Methodology” provides an overview of the topic. It explores the need, the objectives, research hypothesis & limitations of the study. It explains the research methodology adopted.
The third chapter reviews various aspects of “Clinical Trials”. It provides a brief history of evolution of concept of clinical trials. It explores the various types of clinical trials. Further, the chapter discusses about vaccine clinical trials and its phases. The chapter moves on to give an overview of the clinical trial scenario in India, with special emphasis to the advantages in conducting clinical trials in India and concerns expressed against it. The chapter culminates with a query, of how prepared is India for HIV vaccine clinical trials at present.

The fourth chapter titled “HIV Vaccine Clinical Trials” proceeds on the following framework as to equip the reader to better understand the ethical issues unique to HIV vaccine clinical trials.

- The present state of HIV/AIDS pandemic
- Unique characteristics of HIV
- Basic nature of Human Immune System
- Various kinds of vaccines and how they work

This chapter is thus outlined in such a way that the reader proceeds with ease from one concept to another with clarity of thought. The chapter then examines the spectrum of possible strategies for use of HIV vaccines. It further moves on to explain the safety implications of various types of HIV vaccines. Further the chapter explores the various challenges (scientific, ethical, legal and economic) contributing to the delay in the development of an effective HIV vaccine after three decades of stringent research. The chapter elaborates the ethical issues unique to HIV vaccine clinical trials at length.

Having seen the ethical issues pertaining to clinical trials of HIV vaccines, we move on to chapter five which summarizes the “Legal Frame Work To Regulate Clinical Trials”. This chapter is further subdivided into legal framework internationally, the evolution of regulations pertaining to clinical trials, various guidelines with regard to Good Clinical Practice and regulations applicable to clinical trials in India. The researcher attempts to broadly examine the regulatory framework for clinical trials in European Union and United States
of America. Further the researcher critically explains the regulations pertaining to clinical trials in India – more so to that of HIV vaccine clinical trials. The chapter elaborates as to how, due to lack of or weak regulations, the HIV vaccine clinical trial scenario has gone bad.

Chapter six titled “Suggestions for Policy Reforms” puts forth few suggestions which if incorporated would make the rather grim scenario of HIV vaccine clinical trials better.

Finally, the concluding chapter sums up the research work hoping the present scenario would change soon, and India would be able to address the issues effectively and a much awaited vaccine would happen soon.

(b) Citation:

NLS Guide to Uniform Legal Citation was followed in citing the references. A list of cases referred has also been listed in an alphabetical manner at the end of the thesis. For ready reference, foot noting is done. The URLs of internet search done have also been cited.

(c) Appendices:

The questionnaire cum opinionnaire sent to various departments and personals for the current study, the responses , a model Bill of Rights and Responsibilities of Participants as proposed by Thomas Kerns and a HIV Preventive Vaccine Clinical Trial Protection Of Participants Bill, 2015 proposed by the scholar are appended at the end of the thesis.