1. **Jessika van Kammen, (2000)** In this article the author discuss the ethics of medical research. In Particular the author argue that the ethics of clinical testing are not confined to the recruitment stage and information provided to the participants. The author specifies for a more process oriented perspective on the ethics of trial participants involvement. The author concludes by making certain recommendations relating to informed consent. The key issue is providing of clear and adequate information. The ethics committees should intensify their surveillance of medical research. The ethicality of their participation should play a role in the selection of trial centres. Persons who can represent the research participants perspectives should be involved in the planning, organization, and evaluation of clinical trials.

2. **Prathap Tharyan, (2007)**. The author discusses ethical and moral reasons behind registering of medical research, the clinical trial registry of India’s requirements of prospective registration, disclosure of all 20 items in the WHO Trial Registration Data Set and proof of ethics and regulatory clearances. The author suggest that trial registration, by virtue of declaring the presence of a trial and declaring details of the trial protocol, can form the basis for further research. Registration can also help to inform future research subjects or patients, enlighten those who plan or fund new proposals and reduce duplication of effort and duplicate publication.

3. **Prasanta Raghab Mohapatra, Deepak Aggarwal, (2009)** The author says the ethical conduct of a clinical trial does not end with the formulation of a study design and obtaining a signature on an informed consent form. Fatal adverse experiences for subjects in clinical trials should be scrutinised. There are many difficulties in establishing the cause of death. The author concludes by saying that honest investigators who are primarily interested in expanding knowledge and research may result in undue stress, leading to their refusal to conduct future trials. We must protect patients enrolled in
clinical trials, but we must find better ways to protect professionals also. If we do not, the progress of medical research in India may come to a standstill, particularly in controversial and distressing areas.

4. **Nundy S, Gulhati CM. (2005)** The author discusses about advantages and disadvantages of conducting clinical trials in India. He also explains certain safeguards adopted for the protection of human beings after liberalism. He opines that, having benefited from basic and clinical research done primarily in western countries on western populations, we should welcome the opportunity to conduct trials in India and use the experience to enhance our research capabilities. This will not only benefit the research community and industry but also the ripple effect will enhance clinical practice standards for all.

5. **C M Gulhati ,( 2004)** The author speaks about legal requirements for conducting clinical trials. All clinical trials requires DCGI permission and approval by the concerned hospital ethical committees. Research can only be conducted at recognised centres by duly qualified and experienced investigators. In practice, the DCGI approves clinical trials the same way as ration cards are issued by food inspectors. The author concludes by saying that most clinical trials in India are Conducted without any arrangement for compensation in case of study – related injury , disability or even death in human subjects.

6. **Mohanan Nair, Douglas K Martin, (2004)** This paper presents a discussion on ethical review of medical research in India. The authors also points out the problems that need to be addressed. The limitations of ethical review in India is also discussed. Interventions made by the ICMR to improve the ethical review of research like developing general research guidelines and also some specific areas of research are also discussed. The Paper is concluded with the observation that institutional mechanisms for ethical reviewing of research involving human participants in India are weak and vulnerable. A concerted effort is required to strengthen them to fulfil their stated missions.
7. **Vishwas H Devaiah, (2010)** This paper examines the impact of bioethics on patent claims. The increase in research activities involving human biological materials, and the rush to commercialise inventions derived from such biological materials, can at times result in unethical conduct of research. Questions arise as to whether patent law should concern itself with tainted research that has resulted in an invention or whether it should grant patent rights solely on the basis of the technical improvements resulting from such research. This paper highlights the significance of ethical practice in biomedical research, an issue that may influence the decision to grant patents on inventions. It explores the relation between morality, bioethics and patents from the perspective of the objectives of the patent system and current developments in the law on patents. The inclusion of the morality provision in patent law introduces a mechanism through which inventions derived from tainted research can be filtered at an early stage.

8. **Ruth Macklin, (2009)** The author asks the question why the World Medical Association, which issues the Declaration decided to make changes again so soon. He opines that powerful forces might have exerted pressure on the WMA to change some key provisions that were viewed as unfriendly to industry and other major sponsors of multinational research. He says the most salutary improvement is in the paragraph that stipulates when it is ethically acceptable to use placebos in a control arm of a randomised, controlled clinical trial.

9. **Gagandeep Kang, (2012)** The author discusses certain areas of concerns which includes ensuring that consent is truly informed, and monitoring participant safety, the occurrence of deaths, and the payment of compensation. He also discusses about the draft guidelines for compensation for impairment of disability. The author opines that it is commendable that the government of India is taking steps to safeguards the rights of research participants and emphasise the responsibility of sponsors, investigators and institutional ethics committees engaged in conducting or reviewing clinical research in India.
10. Sue Eckstein, (2001) The author discusses certain aspects of healthcare research that can be particularly problematical for members of research ethics committees is that of research involving vulnerable groups. These include children, the mentally ill, elderly people and the dying. The author argues that Putting aside the legal issues relating to consent, there is a moral requirement to involve a child as much as possible and/or appropriate in the consent process. This entails a number of specific duties when there is the possibility that the child could participate in a meaningful way. They include testing the individual child’s ability to participate in the consent process and proceed accordingly, ascertaining the extent to which the child wishes to be involved in the decision making process, discussing with the parents or guardians the extent to which they are prepared to involve the child in the process and final decision and providing information which will help the child to get a realistic sense of what will be involved in participating without causing undue harm. The author concludes by stating that, the key to success in gaining informed consent lies in effective communication between researchers, families, associated professionals, professional bodies, LRECs and MRECs, research councils, charities, drug companies and educational institutions, and possibly parental or patient involvement in the design of the project.

11. Jansen L A, (2014) The author draws on the concept of “mindset” from social psychology and elaborates on the distinction between deliberative and implementation mindsets to understand why people suffer from therapeutic error. When faced with two goals, while a person with a deliberative mindset will try to accurately assess the outcome of each and decide accordingly, a person with an implementation mindset will keep planning about the outcomes of the goals. So, it is the former who can make more accurate predictions about any future course of action. The author argues that chances of therapeutic error are higher among people with an implementation mindset, than among those with a deliberative mindset.

12. Vasantha Muthuswamy (2014) The author says that it is interesting to take stock of the evolution of the DoH over the years. The first version was released by the WMA in 1964 at Helsinki in Finland, following the crisis in research ethics during World War II. The
first revision was made in Tokyo, Japan in 1975. This was twice the length of the original, which had 11 articles and 713 words. It was this version which first introduced the concept of an independent committee to review research proposals. The latest (2013) in the series is the newly announced seventh version. Although this version contains no radical changes, it is definitely more readable. For the first time, the vital principles are placed under separate sub-headings, emphasising the importance of these issues. Compared to the original 11 articles in the 1964 version, this version has 37, just two more than the number in the 2008 version. There are 13 articles under the General Principles (3–15), eight under informed consent (25–32), three under risk, burden and benefits (16–18), two each under the preamble (1–2), vulnerable groups and individuals (19–20), and scientific requirements and research protocol (21–22). One article each is devoted to research ethics committees, privacy and confidentiality, the use of placebo, post-trial provisions and unproven therapies.

13. Neelambari Bhosale, (2014) The author discusses about the recent negative media reports on the status of participants in clinical trials in India and certain concerns expressed by the regulatory bodies. The author opines that these concerns have raised questions regarding India’s credibility in the conduct of clinical research. Even though the regulations for the registration of trials with the Clinical Trial Registry and the recently mandated registration of ethics committees (ECs) with the Drugs Controller General of India, the lack of governmental audit and accreditation procedures and bodies has resulted in inadequate protection of human participants in medical research. Institutions and research sites would benefit by implementing a human research protection programme, which would safeguard the rights, safety and wellbeing of participants in clinical trials, in addition to improving the processes and procedures for the conduct of the trial. The authors also suggest the need for a governmental accreditation body, which will be required for the future promotion and improvement in the standards for clinical practice in India.

14. Shankar V Kundapura, Thirtha Poovaiah, Ravindra B Ghooi, (2013) The author discusses about the informed consent process as a shield which protects subjects from
harms that may be caused by a scientific enquiry. Only a competent participant with a complete understanding of the trial can give informed consent. Although the content of a valid informed consent form (ICF) has been established, the Drugs and Cosmetics (First Amendment) Rules, 2013 have stipulated that ICFs must fulfil the requirements of Appendix V of Schedule Y. The authors considered 50 ICFs and analysed whether they complied with Appendix V. The analysis reveals a gloomy picture, with 70% of the ICFs deviating from the requirements of the law. The article is concluded with some recommendations to help the participants to better understand the trial. The findings indicate that adequate action needs to be taken to ensure the protection of the rights of research participants. The informed consent process is the practical application of the principle of autonomy. Informed consent that is given freely is central to ethically sound research. The author specifies that the practical implication of autonomy need to ensure that there is no elements of coercion, deceit or abuse. Informed consent must be obtained in the right manner from participants in research and patients in clinical care.

15. Al-Shahi R, Vousden C, Warlow C,( 2005) The authors, through their observational study, shows how the modern era of data privacy in the UK can seriously prejudice the findings of observational research. Such research is essential to planning effective treatment for and prevention of complications of a chronic disease. The paper is concluded by making certain observations like, differences between adults who consent to participate in observational records-based research and those who do not, or cannot, consent. Blanket requirements for explicit consent for the use of individuals’ identifiable data can bias disease registers, epidemiological studies, and health services research.

16. Shilling V, Young B, ( 2009) The author says about the importance of understanding the parent’s perspective about enrolling a child in a trial. In a qualitative study, the authors found that parents of children with a serious diagnosis were more anxious (than those with less seriously ill children) about the risks and outcomes of a trial. Parents who had little grasp over their child’s disease sometimes felt excessively dependent on clinicians and expressed uneasiness in making an autonomous decision. Parents viewed “randomisation” negatively. They were concerned about the possibility that their child
would be randomised to the less effective treatment and feared the guilt that they would feel if the child later deteriorated. However, trials in neonatology and childhood cancer have high participation rates, suggesting that parents are prepared to take greater risk for the hope of a cure. The authors of this article note that researchers conducting trials with children would benefit from a better understanding of the special situations of parents and their particular needs. They could then help parents retain the sense that they had safeguarded their child’s interests. The authors points out that research is needed in whatever cost and pertinent issue is how to make a better understanding of the needs of the parents in practice.

17. Sisira Siribaddana Wasantha Bandara, (2013) The author defines Medical Research as studies involving human participants, with the intervention being selected by the investigator which is either related to a new drug or device, or a new indication for an already approved drug or device. The intervention can also relate to different healthcare options, eg the trial may be aimed at comparing the management of a particular illness in the hospital to its management in the community. The state regulatory body for drugs in Sri Lanka is the Cosmetics Drugs and Devices Regulatory Authority (CDDRA). The CDDRA’s permission is required for the registration and import of new drugs. In January 2009, the ministry of health appointed a subcommittee on clinical trials (SCOCT) under the CDDRA. The SCOCT’s regulatory approval is necessary for clinical trials. The SCOCT requires ethical approval by a recognised ethics review committee (ERC). Further, according to the regulations, registration in the primary World Health Organization clinical trial registry network is mandatory. The clinical trial registry, which is in the premises of the Sri Lanka Medical Association, is the only such registry in the country. Recently, bureaucrats in the health and the finance ministries, as well as a few academics, have been pushing for a new Act on clinical trials. This paper highlights the various loopholes in this draft Act and describes how it may give the pharmaceutical companies opportunities to circumvent its provisions and exploit patients. The author opines that, as in the USA, this Act will protect contract research organisations (CROs) and clinicians from law suits in case of an injury to a participant.
18. **Hans Jonas (1969)** In this article the author Hans Jonas discusses about the complexity of the subject of human experimentation. He says the subject is obscure by its nature and involves fundamental and trans technical issues. The author explains the peculiarity of human experimentation, conflict between the ideas of individual good and the common good, the long range interest of the society, science and progress on one hand and the rights of the individual on the other. The author also discusses the sacrificial and social contract theme. He opines that, health may be considered as a public good and medical research as a cause of progress.

19. **Alexander Morgan Capron (1999)** The author opines that the object of science is to understand human beings and eventually humans become the experimental animal of necessity. He says in the research with human beings, the category of vulnerable seems almost limitless. The author specifies that, the time has come for a paradigm shift, not simply evolutionary adjustments of the details of the regulations but a new way of developing. As in the USA, this Act will protect contract research organisations (CROs) and clinicians from law suits in case of an injury to a participant, promoting, monitoring and revising the regulations.

20. **Paul R. Benson (1989)**, The author discusses certain concerns which resulted in calls for increased governmental control over the activities of physicians and scientists like, 1. The belief that medicine, law and science possess unique expertise and are oriented primarily towards the public good, have gained an autonomy. 2. Public ambivalence towards science has also risen as technological and biomedical advances to deal with the social, economic and ethical dilemmas. The author suggests a study to examine the interactive effects on investigators ethical attitudes and practices.

21. **Tomossy George F. and Weisstub David N. (eds), (1995)** In this paper the author argues that the principles of Belmont Report and the Beauchamp and childress can provide a foundation for the source of ethical appraisal of human research. They are not wholly adequate. These principles should be understood as heuristics and must be combined with principle-based approach incorporating sensitivity to the context of evaluation of clinical trials.