BIBLIOGRAPHY
<table>
<thead>
<tr>
<th>Sl.no</th>
<th>BOOKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>D. Wangand A. Bakhai, <strong>CLINICAL TRIALS: A PRACTICAL GUIDE TO DESIGN ANALYSIS AND REPORTING</strong>, Remedia, Medical Education and Publishing (1st edn., 2006).</td>
</tr>
</tbody>
</table>
ONLINE NEWS


REFERENCES- POLICIES/ STATUTES, Misc…


2. BELMONT REPORT(1979), Ethical principles and Guidelines for the protection of human subjects of Biomedical and Behavioral research,


4. Code of Federal Regulations

5. CDSCO Order File no 12-01/14/47/ Pt .47 dated 03-07-2014,

6. CDSCO, Placebo Controlled Trials, Reg, File no 12-01/14DC .Pt.47 , dt .03-07-2014


21. Drugs and Cosmetics Act, 1940.
22. Drugs and Cosmetics Rules, 1945.
23. The Epidemic Diseases Act, 1897.
26. EC Regulation No. 2309/93.
30. ICMR, Ethical Guidelines For Biomedical Research On Human Participants, New Delhi, 2006.
31. EU Clinical Trial Register.
32. European Commission, European Research on HIV/ AIDS.
33. European Medicines Agency, Questions and Answers on EMA Policy on publication of clinical data for medicinal products for Human Use.
34. Federal Food, Drugs Act 1906.
42. CIOMS, Guidelines For Biomedical Research Involving Human Subjects.
50. Indian Penal Code, 1860.
52. Medical Council of India Act, 1956.
55. National Health Bill.
58. National Vaccine Policy 2011
66. The Patient Protection and Affordable Care Act (PPACA).
69. US FDA, FDA’s Role : Clinical Trial.gov information, Vaccine Injury Compensation Program.

UN MATERIALS

Sl.no

1. A. Wodak. The Challenge of HIV spread among and from Injecting Drug Users in Asia. DEVELOPMENT BULLETIN No 52. UNAIDS Asia Pacific Inter Country Team.
9. S. Kippax, HIV And Technology : The Issue Of Prophylactic Vaccines ,DEVELOPMENT BULLETIN No 52 , June 2000 ,UNAIDS Asia Pacific Inter country Team.
10. UN AIDS Technical Updates, Population Mobility and AIDS, 2001
11. UN Economic and Social Council, RESOLUTION 1994/24, Joint and co-sponsored United Nations programme on Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome (HIV/AIDS),
16. UNAIDS 2011- 2015 STRATEGY.
17. UNAIDS Face sheet on Stigma and Discrimination.
18. UNAIDS Guidance Document May 2000 : Ethical Considerations in HIV Preventive Vaccine research
20. UNAIDS, AIDS Epidemic Update,( November 2008 )
21. UNAIDS, Country Progress Report
22. UNAIDS, GOOD PARTICIPATORY PRACTICE , GUIDELINES FOR BIO MEDICAL HIV PREVENTION TRIALS , 2011 UNAIDS / JC1853E (2Edn, June 2011)
23. UNAIDS, HIV-Related Stigma And Discrimination: A Summary of Recent Literature ( AUGUST 2009),
24. UNAIDS. Ethical considerations in Biomedical HIV Prevention Trials (Additional Guidance Point added in 2012)
26. UNITED NATIONS Development Program, Facts and Figures on Povert

Sl.no. REFERENCES - WORKING PAPERS/ WHITE PAPERS

2. White Paper on 'Global Clinical Trials in India – prospects and challenges', Cygnus Business Consulting and research

Sl.no. INTERNET SOURCES


32. B.M. Moier, International Protection Of Persons Undergoing Medical Experimentation: Protecting The Right Of Informed Consent. BERKELEY JOURNAL OF INTERNATIONAL


ng_on_European_clinical_trials_powerpoint_ppt_presentation (Last visited on December 12, 2014).


165. T. Lemmens, & R. Bouchard, Comments on the Legal, Regulatory and Ethical Aspects of the WHO Clinical Trial Registry Platform, Submitted as part of the Formal Consultation on


