

نظری بر کمیته‌های اخلاق در پژوهش در جهان و ایران

*

چکیده

»

«

«

»

واژگان کلیدی:

* نشانی:

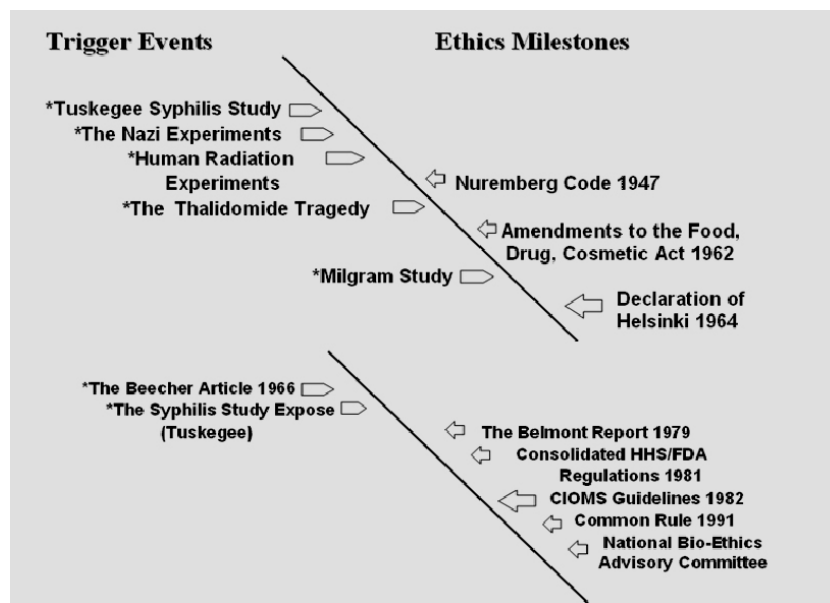
emrc@tums.ac.ir :

:

:

تاریخ دریافت مقاله: ۸۵/۴/۶

تاریخ پذیرش مقاله: ۸۵/۶/۲۰



شکل ۱- سیر زمانی وقایع و شواهد تاریخی منجر به تدوین قوانین اخلاقی و بیانیه‌های بین‌المللی برگرفته از: Dunn CM, Chadwick GL, Protecting study volunteers in research Boston: Center Watch 2004.

شواهد تاریخی و قوانین بین‌المللی

)

(

:

.[]

.[]

.[]

.()

()

Tuskegee

()

()

()

()

()

.[]

⁴ The WMA General Assemblies, Helsinki, Finland, 1964; Tokyo, Japan, 1975; Venice, Italy, 1983; Hong Kong, 1989; Somerset West, Republic of South Africa, 1996; Edinburgh, Scotland, 2000; Note of Clarification on Paragraph 29, Washington 2002; Note of Clarification on Paragraph 30, Tokyo 2004.

⁵ Placebo-controlled Clinical Trials

⁶ <http://www.wma.net/e/policy/b3.htm>

¹ <http://www.hhs.gov/ohrp/references/nurcode.htm>

² <http://www.wma.net/e/policy/b3.htm>

³ <http://ohsr.od.nih.gov/guidelines/belmont.html>

[]

(CIOMS)

(WHO)

[]

« » CIOMS []
: []

:

«Science»

:

)

(

:

[]

()

[]

³ Quality

⁴ Efficacy

⁵ Safety

⁶ International Conference on Harmonization (ICH)

⁷ Guidelines of Good Clinical Practice (GCP)

¹ <http://www.cioms.ch/index.html>

² The burdens and benefits

) : []
(
.[]

کمیته‌های اخلاق در پژوهش

[]

Institutional) IRB (Ethics Committee) EC
(Ethics Review Committee) ERC (Review Board

[]

() /
()
%

[] %

[]

[]

Nuffield

() []

(NBAC)

[]

² Data and Safety Monitoring Committees
³ The Regulatory Authority

¹ National Bioethics Advisory Council

:[]

:[]

« »

.[]

:[]

.[] (PMAs)

)

((HPAs)

(NGOs)

.[]

(HECs)

(RECs)

-
- ¹ Protection
 - ² Advice
 - ³ Education
 - ⁴ Research Quality
 - ⁵ Conciliation
 - ⁶ The United Nations Educational, Scientific and Cultural Organization (UNESCO)
 - ⁷ Policy-Making and/or Advisory Committees (PMAs)
 - ⁸ Health-Professional Association Committees (HPAs)
 - ⁹ Health care/Hospital Ethics Committees (HECs)
 - ¹⁰ Research Ethics Committees (RECs)

-
- ¹¹ Autonomy
 - ¹² Non-governmental Organizations
 - ¹³ The Danish Council of Ethics
 - ¹⁴ The Ethics Committee of the Gambia

[]

)

(

[]

[]

(OHRP)

%

[]

[]

مسئولیت‌های پژوهشگر و بانی تحقیق

[]

¹ Office for Human Research Protections(OHRP)

:

« »

« »

)

(

[]

)

.(

[]

()

()

³ Legal Competency

¹ Scientific validity

² Capacity

)

(

[]

آموزش اخلاق در پژوهش

[]

« » « »

[]

[]

² Problem-based approach

³ Multidisciplinary

¹ Pilot-testing

[]

[]

[]

(OHRP)

[]

کمیته‌های اخلاق در پژوهش در کشور

[]

[]

»

«

: ()

«

»

¹ online
² E-learning
³ Family Health International (FHI)
⁴ National Institute of Health (NIH)
⁵ Self-education-5
⁶ www.ethics.hbi.ir or www.mehr.tums.ac.ir
⁷ Eastern Mediterranean Health Journal
⁸ Developing World Bioethics
⁹ Bioethics

)

(

()

.()

() :

()

.()

[]

.()

.()

.()

:

.()

...

PhD

:

(OHRP)

.()

« »

1

.()

()

.()

وضعیت رعایت اصول اخلاق در پژوهش در کشور

()

(% /)

()

()

[]

%

(%)

%

(% /)

(/)

(/)

[]

%

[]

%

%

تدوین راهنمای ملی اخلاق در
پژوهش‌های علوم پزشکی

%

[]

¹. Externally-Sponsored Research (ESR)

)

(
[]

نتیجه‌گیری

()

۵
۶

¹ www.ethics.hbi.ir or www.mehr.tums.ac.ir

مآخذ

2. Dunn CM, Chadwick GL. *Protecting study volunteers in research*, 3rd Edition. Boston: Center Watch; 2004.
3. Schuklenk U. Module one: introduction to research ethics. *Developing World Bioethics* 2005; 5: 1-13.
4. *The Nuremberg Code* 1947. <http://www.hhs.gov/ohrp/references/nurcode.htm> (Reprinted from "Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.) (Updated May 2006).
5. World Medical Association. *Declaration of Helsinki: Ethical principles for medical research involving human subjects*. France: The World Medical Association. <http://www.wma.net/e/policy/b3.htm> (Updated May 2006).
6. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. April 18, 1979. <http://ohsr.od.nih.gov/guidelines/belmont.html> (Updated May 2006).
7. The council for International Organizations of Medical Sciences. *International Ethical Guidelines for Biomedical Research involving Human subjects*. Geneva: CIOMS, 2002. <http://www.cioms.ch/index.html> (Updated May 2005).
8. World Health Organization, WHO Technical Report Series, No. 850, 1995, Annex 3. *Guidelines for good clinical practice (GCP) for trials on pharmaceutical products*. <http://www.vghtpe.gov.tw/~mre/goodexp/Fercap-Survey/WHO-GCP-1995.pdf> (Updated May 2005).
9. International Conference on Harmonization (ICH), *Guidelines for Good Clinical Practice in clinical trials*. <http://www.mrc.ac.uk/pdf/ctg.pdf> (Updated May 2005).
10. International Conference on Harmonization (ICH), *Guideline for Good Clinical Practice. Note for Guidance on Good Clinical Practice*. 2002. <http://www.emea.eu.int/pdfs/human/ich/013595en.pdf> (Updated May 2005).
11. Hwang WS, Ryu YJ, Park JH, Park ES, Lee EG, Koo JM, et al. Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. *Science* 2004; 303: 1669-74.
12. Hwang WS, Roh SI, Lee BC, Kang SK, Kwon DK, Kim S, et al. Patient specific embryonic stem cells derived from human SCNT blastocysts. *Science* 2005 17; 308: 1777-83.
13. News. Dr. Hwang Dropped from Scientific American 50 for Faking Research. *Scientific American* 2005; 15. http://sciam.com/print_version.cfm?articleID=000D550E-D624-13A1-962483414B7F0000 (Updated Oct 2006)
14. <http://www.sharghnewspaper.com/841101/html/da4.htm> (Updated February 2006).
15. Harvard Project in China Violates Farmers' Rights, *People's Daily Online* 2002(May 2). <http://english.peopledaily.com.cn> (Updated July 2006).
16. John Hopkins University Office of News and Information. Hopkins Scientist Sanctioned Over Drug Trial in India. 2001 (November12). http://www.jhu.edu/news_info/news/home01/no-v01/India.html (Updated March 2005)
17. Guenter D, Esparza J, Macklin R. Ethical considerations in international HIV vaccine trials: summary of a consultative process conducted by the Joint United Nations Programme on HIV/AIDS(UNAIDS). *J Med Ethics* 2000; 26: 37-43.
18. Edejer TT. North South research partnerships: the ethics of carrying out research in developing countries. *BMJ* 1999; 319: 438-441.
19. Ad Hoc Committee on Health Research. *Investing in health research and development*. Geneva: World Health Organization; 1996.
20. *The 10/90 report on health research 2000*. Geneva: Global Forum for Health Research; 2000.
21. The Nuffield Council on Bioethics. *The ethics of research related to health care in developing countries*. London: Nuffield Council on Bioethics, 2002. <http://www.nuffieldbioethics.org/go/ourwork/developingcountries/introduction> (A follow-up Discussion Paper was also published in 2005: <http://www.nuffieldbioethics.org/>) (Updated February 2006).
22. National Bioethics Advisory Commission. *Ethical and policy issues in international research*. Washington (DC): National Bioethics Advisory Commission; 2000. <http://www.georgetown.edu/research/nrcbl/nbac/pubs.html> (Updated February 2006).

23. Dhai A. Module five: implementation of ethics review. *Developing World Bioethics* 2005; 5: 73-91.
24. Gelling L. Role of the research ethics committee. *Nurse Educ Today* 1999; 19: 564-9.
25. The United Nations Educational, Scientific and Cultural Organization. *Guide N°.1. Establishing Bioethics Committees*. Paris: UNESCO, 2005. <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf> (Updated April 2006).
26. The United Nations Educational, Scientific and Cultural Organization. *Guide No. 2. Bioethics Committees at Work: Procedures and Policies*. Paris: UNESCO, 2005. SHS/BIO-2005/10. <http://unesdoc.unesco.org/images/0014/001415/141563e.pdf> (Updated April 2006).
27. McCormick RA. Ethics Committees: promise or peril? *Law, Medicine and Health Care* 1984; 12: 150-155.
28. The United Nations Educational, Scientific and Cultural Organization. *Guide N°.1. Establishing Bioethics Committees, Appendix I*. Paris: UNESCO, 2005. <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf> (Updated May 2006).
29. The United Nations Educational, Scientific and Cultural Organization. *Guide N°.1. Establishing Bioethics Committees, Appendix 2*. Paris: UNESCO, 2005. <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf> (Updated May 2006).
30. World Health Organization. *Operational guidelines for ethics committees that review biomedical research*. Geneva: WHO, 2000, TDR/PRD/ETHICS/2000.1. <http://www.who.int/tdr/publications/publications/pdf/ethics.pdf> (Updated May 2006).
31. World Health Organization. *Surveying and Evaluating Ethical Review Practices: a complementary guideline to the Operational guidelines for ethics committees that review biomedical research*. Geneva: WHO, 2002, TDR/PRD/ETHICS/2002.1. <http://www.who.int/tdr/publications/publications/pdf/ethics2.pdf> (Updated May 2006).
32. United Nations Educational, Scientific and Cultural Organization (UNESCO). *Universal Declaration on Bioethics and Human Rights*. 19 October, 2005. http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration_EN.pdf (Updated May 2006).
33. Kirigia JM, Wambebe CH, Baba-Moussa A. Status of national research bioethics committees in the WHO African region. *BMC Medical Ethics* 2005, 6:10 (doi:10.1186/1472-6939-6-10).
34. Hearnshaw H. Comparison of requirements of research ethics committees in 11 European countries for a non-invasive interventional study. *BMJ* 2004; 328; 140-141.
35. Ashcroft RE, Newson AJ, Benn PMW. Reforming research ethics committees. *BMJ* 2005; 331;587-588.
36. Olde Rikkert MGM, Lauque S, Frlich L, Vellas B, Dekkers W. The practice of obtaining approval from medical research ethics committees: a comparison within 12 European countries for a descriptive study on acetylcholinesterase inhibitors in Alzheimer's dementia. *Eur J Neurol* 2005; 12: 212-7.
38. Family Health International. *Research Ethics Training Curriculum*. www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm (Updated May 2006).
39. Larijani B, Zahedi F, Malek-Afzali H. Medical ethics activities in Iran. *Eastern Mediterranean Health Journal* (EMHJ) 2005; 11: 1061-1072.
40. Larijani B, Malek-Afzali H, Zahedi F, Motevaseli E. Strengthening Medical Ethics by Strategic Plan in Islamic Republic of Iran. *Developing World Bioethics* 2006; 6: 106-110.
41. Larijani B, Zahedi F. Islamic perspective on human cloning and stem cell research. *Transplantation Proceedings* 2004; 36: 3188-9.
42. Larijani B, Zahedi F, Taheri E. Ethical and legal aspects of organ transplantation in Iran. *Transplantation Proceedings* 2004; 36: 1241-4.
43. Akrami SM, Osati Z, Zahedi F, Raza M. Brain death: recent ethical and religious considerations in Iran. *Transplantation Proceedings* 2004; 36: 2883-7.
44. Larijani B, Zahedi F, Ghafouri Fard S. Rewarded gift for living renal donors. *Transplantation Proceedings* 2004; 36: 2539-42.
45. Larijani B, Zahedi F, Taheri E. Deceased and Living Organ Donation in Iran. *American Journal of Transplantation* 2006; 6: 1493.

