

# 새로운 형태의 환자동의서

## The New Types of Informed Consent

388 - 1

Jang Han Kim, M.D.

Department of Medical Humanities and Social Sciences

University of Ulsan College of Medicine

E - mail : jhk@amc.seoul.kr

### Abstracts

Informed consent is an essential issue in medical practice. Recently, new types of informed consent have emerged from doctor - patient relationship. Genetic studies using patients' specimens are regulated by the "Bioethics and Biosafety Act", which mandates every genetic study be performed with given written informed consent. Clinical trials for drug development are regulated by the Korea Good Clinical Practice, which requires a review and approval process by the Institutional Review Board. Organ donation is regulated by the "Organ Donation Act". Informed consent from family members is important for organ donation of the deceased and minors. It is recommended that terminally ill patients have advance directives, but we do not have relevant legislation on this. New types of informed consent stress the justifiable intervention of the Parens Patriae and neutral third party. Along with the legalization, these should be summarized to prevent unnecessary conflicts.

**Keywords** : Informed consent; Genetic study; Clinical trial; Advanced directives; Organ donation

가  
가  
가  
가  
(Human  
rights)  
10  
“ ... ”

가 , . ,  
가 , 가 ,  
가 . 가 ,  
가 . 가 ,  
가 . 가 ,

가 , 1)  
가 . 20 . ,

가 .

3 가 “ ,  
가 (hospital ethics committee) ”  
가 가 ,

가 .

2) 2005 “ ( 가  
 )”

가 .<sup>1)</sup>  
가

가 . 가

---

1)

[ 20 ]

( )

( 17 2 )


1. ( ) :
  2. : \*\* \*\*
  3. : \*\* 5 \*\* 가 : ( )
  4. :  
\*\* \*\*
  5. :  
\*\* \*\*
- 1) . . . . . \*\*
  - 2) 12 . . . . . \*\*
  - 3) . . . . . \*\*
  - 4) 가 . . . . . 가
  - 5) . . . . . 가
  - 6) . . . . . 10 . . . . . \*\*

-----  
-----  
-----

210mm x 297mm( 60g/m<sup>2</sup>)

가 .“ .

( 20 , 가 ” ,  
17 2 ) ( 1). 2~5  
가

“1. ( ) , 2. 가 .  
( , ), 3. ,  
(5 , 가 ) , 4.

( , ) 5. 1 ‘ ’ 가

( , )” 가 .

“

( ) “1) ‘ ,

. 2) .

12 (experiment) (therapeutic)  
....” 가

가 ,

가 .

가 가 2) .

가 . 2 가 .

(Code of Nuremberg) , (Institutional review board, IRB)  
 (Declaration of Helsinki) ,  
 . Henry Beecher가 1966  
 NEJM “ Ethics and Clinical research ” .<sup>2)</sup>  
 22 , (typhoid fever) 3)  
 (chloramphenicol) (Clinical trial) .  
 22.9% , 가 .  
 7.97% . Elixir sulfanilamide 100  
 , 4 1 3 가 ,  
 가 .  
 , 3 1938 , (Food, Drug  
 Jewish Chronic Disease Hospital , the and Cosmetic act, FD&C act)  
 Willowbrook . 1950  
 .<sup>3)</sup>, 1960 (Thali domide)  
 (Tuskegee syphilis study)가  
 (The , 1990 International  
 Belmont Report; 1979)가 . conference on Harmonization(ICH) .<sup>4)</sup>  
 1953  
 (NIH) 4)  
 가 1966 . 26  
 1970 (U.S. Food and 4  
 Drug Administration, FDA)

( 1 ) .

2) Baruch A. Brody. The Ethics of Biomedical Research. An International Perspective. New York. Oxford, 1998: 35 - 54

3) (1955), (1968), 1950 ( ), 1960 , 1970 . 植木 哲. 医療の 法律學. 有斐閣, 1998: 213 - 42

4) Shein - Chung Chow, Jen - Pei Liu. Design and Analysis of Clinical Trial. 2nd ed. New - Jersey. Wiley - Interscience, 2005: 1 - 34

‘ (Korea Good Clinical Practices, ICH - E6) , (Living donor) KGCP) ’ (Cadaveric donor) .

가

5) , 2 “ 가 가 가 가 liv- ” ing anonymous donation .<sup>5)</sup> ( ) 가가

가

6) , 2) ( ) 가 , 3

가 3 , 가 16 ( 10 3 ). 16

가 4 ( 4 ).

2 1 , , 1) ( 5 )

5) Hoyer JA. Nondirected kidney donation and its consequences: personal experience of a transplant surgeon. *Transplantation* 2003; 76: 1264 - 65

가 2 1 ( 2 ).

, 16 2

16 가 3

( 가 ) ( 가 3 : 18 1 ). ( 가 ) 2

3) , : 1 가 1 가 2

,가 ( 가 ) 1 ( 3 )

( 18 2 1 ) ( 18 3 ).

가 ( 2 ). 4) 16 , ,가

, 가

가 가 가 가 .<sup>6)</sup>

( ,가 11 1 1 ). 2 (가 1 1) 1 ) 가 , 가 , 가

2 . 1970

가 가 1 .

, 가 , , 가

가 ( 1 . 1976

2 ). 가 가 가

6) , 2000: 138

7) American College of Legal Medicine Textbook Committee. Legal Medicine, 6th ed. Philadelphia: Mosby, 2004: 312 - 3

가 . 가  
가 . 가  
. 8)  
(Durable power of attorney)  
가 . 가  
가 . 가  
. (Advance Direc- 가 가  
tives) (Oral) 가 . , 가  
. , ,  
. 1990 (Patient Self  
가 . Determination Act)  
Medicare Medicaid  
(Clear and convincing evidence)  
. .  
. 1990  
2) 가 가 . 7) 43 가  
(Living will) 가 , (Bill of  
Patient)  
. , 가  
3)  
가 .  
가 . 50  
가 가  
가 가  
(Value inventory) . 가 가 . 가

8) Gregory. E. Pence. *Classic Cases in Medical Ethics*. 4ed. New York: Mcgraw Hill, 2004: 53

9) SUPPORT Principal Investigator, "A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients. The study to understand Prognoses and Preferences for Outcpmes and Risks of Treatment(SUPPORT)." *JAMA* 1995; 274: 1591 - 8

가 , 가 가

9) , 가

가 .

가 .

가?

가 20 ,

가 .

가

가 .

가

3

가

가

3 , 가

가

가

10)

(Institutional review

board, IRB)



가

1. Baruch A. Brody. The Ethics of Biomedical Research. An Inter-

10) Uniform Health Care Decisions Act

national Perspective. New York. Oxford, 1998: 35 - 54

2. 植木 哲. 醫療의 法律學. 有斐閣, 1998: 213 - 42
3. Shein - Chung Chow, Jen - Pei Liu. Design and Aanalysis of Clinical Trial. 2nd ed. New - Jersey. Wiley - Interscience, 2005: 1 - 34
4. Hoyer JA. Nondirected kidney donation and its consequences: personal experience of a transplant surgeon. Transplantation 2003; 76: 1264 - 65
5. American College of Legal Medicine Textbook Committee. Legal Medicine. 6th ed. Philidelphia: Mosby, 2004: 312 - 3
6. Gregory E. Pence. Classic Cases in Medical Ethics. 4ed. New York: Mcgraw Hill, 2004: 53
7. SUPPORT Principal Investigator, "A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients. The study to understand Prognoses and Preferences for Outcpmes and Risks of Treatment(SUPPORT)." JAMA 1995; 274: 1591 - 8
8. . . . , 2000: 138

## 8 ( )

1. . . . .
2. . . . .
3. 2~3 가 . . . . .
4. 5 - 가 . . . . .
5. . . . .
6. . . . .
7. 16~17% . . . . .
8. 가 , , 가 . . . . .
9. 5 - . . . . .
10. . . . .