

前 FDA , MD, PhD(leeh@dom.pitt.edu)

2005 誌 가 2, 2004 가 3

가 , Nature 誌 가 4

가 가 가 가 가

가 “... PC 20 가 가 가 가 가 ? ...”

1 2006 2 20 가 SRC (Thou Shalt Not Lie - Research Integrity in Biomedical Sciences)

2 2006 2 17

3 Hwang WS et al., Evidence of a pluripotent embryonic stem line derived from a cloned blastocyst. Science 303, 1669-1674 (2004), Hwang WS et al., Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts. Science 308: 1777 (2005)

4 Ethics and fraud, Nature, 439: 117, 2006

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(Honor System),

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Good Research Practices, ‘

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 , (NIH) ,
 , 가 1985 ‘ (the Health Research Extension Act)’
 ‘ (the Public Health Service Act)’
 493 가 . 493 , 가,
 ,
 , FDA (Public Health Service,
 PHS)⁶ 1970 1980
 , 1986 6 ‘ , ‘ ,
 (Final Rule) 1989 8 , 42 CFR Part 50,
 Subpart A

⁵ (Office of Research Integrity, ORI)
<http://ori.dhhs.gov/about/history.shtml>).

⁶ PHS, (National Institutes of Health),
 (The Centers for Disease Control and Prevention), (The Food and Drug
 Administration), (The Substance Abuse and Mental Health Services
 Administration), (The Health Resources and Services Administration),
 (The Agency for Healthcare Research and Quality), (The Agency
 for Toxic Substances and Disease Registry), (The Indian Health Service)

1986

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(Institutional Liaison Office)’

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1989 3

(Office of Scientific Integrity, OSI)’

(Office of Scientific Integrity Review, OSIR)’

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(conflict of interest)

1992 5

(Office of Research Integrity, ORI)’

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1993 6

(the NIH Revitalization Act of

1993)’

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(Commission on Research Integrity)’가

1995 11

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(whistleblower)

가 ‘ (responsible conduct of research)’

33

1996

Misconduct and Research Integrity)’

(Review Group on Research

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1999

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(National Science and Technology Council)가
(fabrication)
(falsification)
가
(plagiarism)

가 (Office of Inspector General) 가

가 (Division of
Investigative Oversight) (Division of Education and Integrity)

2005 5 17 가 42 CFR Part 93

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(Institutional Review Board, IRB) 가

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(子曰, “道之以政 齊之以刑 民免而無恥. 道之以德 齊之以禮 有恥且格”, 論語, 二編 爲政).”

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(No quality systems, no quality products) 가

“... () () .
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가? , **Good Research Practices** ‘ ,
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가 .

(continuing education) .

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(Research and Practices Fundamentals)

⁷ “ORI monitors institutional investigations of research misconduct and *facilitates the responsible conduct of research (RCR) through educational, preventive, and regulatory activities.*” <http://ori.dhhs.gov/>

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< 1> Good Research Practices

- Educational
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- Preventive
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- Regulatory
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가 , 가
 .⁸ , Good Research
 Practices 가 . , 가
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8 “ 가
 가 . (The trajectory of the Hwang scandal highlights the shortness of the path between unethical behaviour and outright misconduct.), Ethics and fraud, *Nature*, 439: 117, 2006