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Sharing Participant Data Across Borders: Ethical and IRB Concerns

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The Perspectives

- International
- US
- Other countries
  - Canada
  - Australia
  - China
  - Etc.

International Perspective

- Provides a common framework by which all countries can be compared
  - UNESCO
  - WMA

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US Perspective

- Began with Belmont Report
- Force of law
  - 45 CFR 46
  - Common Rule

THE BELMONT REPORT
ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
April 18, 1979

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission

US Perspective

7 CFR Part 1c	Department of Agriculture
10 CFR Part 745	Department of Energy
14 CFR Part 1230	National Aeronautics and Space Administration
15 CFR Part 27	Department of Commerce National Institute of Standards and Technology
16 CFR Part 1028	Consumer Product Safety Commission
22 CFR Part 225	Agency for International Development (USAID)
24 CFR Part 60	Department of Housing and Urban Development
28 CFR Part 46	Department of Justice National Institute of Justice
32 CFR Part 219	Department of Defense
34 CFR Part 97	Department of Education
38 CFR Part 16	Department of Veterans Affairs Office of Research Oversight Office of Research and Development
40 CFR Part 26	Environmental Protection Agency Research and Development
45 CFR Part 46	Department of Health and Human Services
45 CFR Part 690	National Science Foundation
49 CFR Part 11	Department of Transportation

Code of Federal Regulations
TITLE 45 — PUBLIC WELFARE
Department of Health and Human Services

PART 46
PROTECTION OF HUMAN SUBJECTS

Revised June 23, 2005
Effective June 23, 2005

SUBPART A—
Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101 To what does this policy apply?
46.102 Definitions.
46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
46.104-46.106 [Reserved]
46.107 IRB membership.
46.108 IRB functions and operations.

SUBPART B—
Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.
46.201 To what do these regulations apply?
46.202 Definitions.
46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
46.204 Research involving pregnant women or fetuses.

SUBPART D—
Additional Protections for Children Involved as Subjects in Research

Sec.
46.401 To what do these regulations apply?
46.402 Definitions.
46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the in-

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U.S. Office of Human Research Protection (OHRP)

- Provides guidance in all matters related to IRB and human subjects
- Provides for IRB registration
- Issues Federal-Wide Assurances
  - Can be granted to ethics boards in other countries
- Tracks changes in international law and policy
  - Publishes a comprehensive guide, updated annually

OHRP International Compilation of Human Research Standards: 114 pp.

- Seven categories
  1. General, i.e., applicable to most or all types of human subjects research
  2. Drugs and Devices
  3. Research Injury
  4. Privacy/Data Protection
  5. Human Biological Materials
  6. Genetic
  7. Embryos, Stem Cells, and Cloning
- Four Types of Information
  1. Key Organizations
  2. Legislation
  3. Regulations
  4. Guidelines

Example – Canada, general

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
General Note: Several Canadian provinces and territories also have standards on human subjects research.	*National:* 1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. National Defence 3. Correctional Service of Canada			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/ National Defence: Research Involving Human Subjects (1998): http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/text/plcy/cdshtm/009-cde_e.shtml

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Example – Canada, general

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2010

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Compliance with the Policy

To be eligible to receive and administer research funds from the Agencies, institutions must agree to comply with a number of Agency policies set out as schedules to a Memorandum of Understanding (MOU) between the Agencies and institutions.[2] This Policy is referenced in Schedule 2 to that MOU. Institutions must therefore ensure that research conducted under their auspices adhere to this Policy. Researchers are expected, as a condition of funding, to adhere to the TCPS. Institutions should support their efforts to do so.

Example – Canada, privacy/data protection

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection Note: Each of the Canadian provinces and territories has also enacted privacy legislation.	1. Office of the Privacy Commissioner of Canada (OPC): http://www.privcom.gc.ca/index_e.asp 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	1. Privacy Act, Sections 7-8 (1983): http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp	OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (December 13, 2000)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 5: Privacy and Confidentiality (2010) CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/documents/pbp_sept2005_e.pdf

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Lesson 1: Plan Ahead

- Begin planning far ahead of the start date of the research
- Do the research:
  - Ethical standards pertaining to country where data will be collected
  - Legal issues relating to sharing human subjects data
- Make sure the contract is clear on who will hold the data, how it will be shared, how long it will be held
  - Carry through to protocol and informed consent

Lesson 2: Dynamic Field

- But don't plan too far ahead!
- Laws, guidelines, regulations, and policies change frequently, especially when considering multiple countries
- OHRP provides an annual update
  - Check the latest version

Canada: 2010

Australia: 2009

US: Currently considering a major overhaul

Lesson 3: Translation

- Language translation
- Cultural translation

EMBO reports (2006) 7, 850 - 854 | doi:10.1038/sj.embor.7400794

Subject Categories: Ethics | Health & Disease

Bioethics in China

Although national guidelines are in place, their implementation remains difficult

Wolfgang Hennig

The history of bioethics in China is a rather short one: attention was first given to research and medical ethics in the 1960s. obligatory in the 1980s. In 1983, Qiu Xiangxing first published the textbook *Medical Ethics* for Chinese colleges (Qiu, 2005), medical students. The Chinese Association for Medical Ethics was also founded in the mid-1980s, and the Ministry of Publi medical ethics; however, these guidelines were not legally binding regulations. In 1998, the Ministry of Health issued a provi procedures for ethical reviews of any biomedical research involving humans in China. In detail, it regulates topics such as in investigators, the rights of research subjects, and the administrative management of ethical reviews and legal responsibilitie states that ethical reviews are "based upon the principles of ethics accepted by the international community".

"...Chinese regulations and guidelines do not substantially differ from those in Europe or th

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MINISTRY OF HEALTH OF THE PEOPLE'S REPUBLIC OF CHINA

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卫生部关于印发《涉及人的生物医学研究伦理审查办法(试行)》的通知

卫生部关于印发《涉及人的生物医学研究伦理审查办法（试行）》的通知

卫科教发〔2007〕17号

各省、自治区、直辖市卫生厅局，新疆生产建设兵团卫生局，部直属单位，国务院有关部委科研管理部门：

为引导和规范我国涉及人的生物医学研究伦理审查工作，推动生物医学研究健康发展，更好地为人类解除病痛、增进健康服务，我部组织制定了《涉及人的生物医学研究伦理审查办法（试行）》，现印发你们，请遵照执行。

二〇〇七年一月十一日

附件：

涉及人的生物医学研究伦理审查办法（试行）

第一章 总 则

第一条 为规范涉及人的生物医学研究和相关技术的应用，保护人的生命和健康，维护人的尊严，尊重和保护人类受试者的合法权益，依据《中华人民共和国执业医师法》和《医疗机构管理条例》的有关规定，制定本办法。

第二条 涉及人的生物医学研究伦理审查工作均按照本办法组织进行。

第三条 本办法所称涉及人的生物医学研究和相关技术应用包括以下活动：

（一）采用现代物理学、化学和生物学方法在人体上对人的生理、病理现象以及疾病的诊断、治疗和预防方法进行研究的活动；

（二）通过生物医学研究形成的医疗卫生技术或者产品在人体上进行试验性应用的活动。在本办法施行前已在临床实

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Lesson 4: Satisfy All Sides

- Now – and into the future
- Abide by relevant laws, policies, guidelines
- Abide by the contract
- Uphold promises made to research participants
- Protect the data
  - Hold it securely
  - Share it according to agreed upon conditions

Resources

- OHRP Compilation
  - http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html
- Belmont Report
  - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
- US Code of Federal Regulations
  - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- Other resources available upon request:
  - Suzie Lee, slee@vtti.vt.edu