PRIVACY and CONFIDENTIALITY of HEALTH RESEARCH INFORMATION

Renato B. Manaloto
University of the Philippines Diliman

OBJECTIVES

1. To distinguish between health and non-health information;

2. To identify the ethical and regulatory principles and requirements in protecting the privacy of research participant and ensuring the confidentiality of participant's health information; and

3. To link the roles and responsibilities of the researchers with those of the ethics review committees in providing this protection.

OVERVIEW

I. Health Information v. Non-health information

II. Kinds of Health Information

III. Privacy and Confidentiality

IV. Ethical Principle for Privacy and Confidentiality

V. Legal Principles for Privacy and Confidentiality

VI. Privacy and confidentiality under International Ethical Guidelines

VII. Ethically- and legally-valid disclosures of health information

VIII. Responsibilities of Researchers and ERCS

I. Health v. Non-Health Information (1)

Health information is information in **any form or medium** (paper, electronic, and images such as x-rays or sonograms) that **relates to a living or deceased individual's past, present or future physical or mental health or condition, provision or payment of healthcare.**

--US Privacy Rule

I.Health v. Non-Health Information (2)

Non-health information is information in any form or medium that **does not relate to living or deceased individual's physical, mental or health condition, or health care provision or payment.**

(e.g., biological specimens in and of themselves are not health information.)

II. Kinds of Health Information (1)

1) Individually Identifiable

They directly identify the individual or reasonably could be used to identify an individual.

2) De-identified

Those without individual identifiers.

II. Kinds of Health Information(2)

Identifiers

1. Names
2. All geographic information
3. All elements of dates (except year), including birth, death admission and discharge dates
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers

II. Kinds of Health Information(3)

Identifiers

11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images, and
18. Any other unique identifying number, characteristic or code.

III. Privacy and Confidentiality

Privacy is the right of persons not to share information about themselves.

--Dunn and Chadwik, 2004

Confidentiality is the obligation to keep private information that has been collected from being shared with others.

--Dunn and Chadwick, 2004

IV.Ethical Principle

"For all rational beings come under the law that each of them and all others must be treated never merely as means but in every case at the same time as ends in themselves."

(Kant, Groundwork for the Metaphysics of Morals, 1785)

Respect for persons connotes respect for privacy of persons and confidentiality of information.

V. Legal Principles

A legal right to privacy can be **derived from fundamental rights to life, liberty and property** and ...largely from the **right to enjoy life--the right to be let alone.**

--Warren and Brandeis, 1975

"A doctor shall preserve absolute secrecy on all he knows about his patient **because of the confidence entrusted to him."**

--International Code of Medical Ethics
(Declaration of Geneva)

VI. International Ethical Guidelines (1)

A. Declaration of Helsinki

Every precaution should be taken to **respect the privacy of the subject, the confidentiality of the patient's information** and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

-- Paragraph 21

B.CIOMS Guidelines

The investigator must establish **secure safeguards of the confidentiality of subjects' research data.** Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

--Guideline 18

VI. International Ethical Guidelines(2)

C. ICH- Good Clinical Practice

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected (1.24)

The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s) (2.11)

VI. International Ethical Guidelines (3)

D.WHO Operational Guidelines for Ethics Committees That Review Biomedical Research

Protection of Research Participant Confidentiality

a description of the persons who will have access to personal data of the research participants, including medical records and biological samples (6.2.4.1)

the measures taken to ensure the confidentiality and security of personal information concerning research participants (6.2.4.2)

VI. International Ethical Guidelines (3)

E. International Declaration on Human Genetic Data

States should endeavour to **protect the privacy of individuals and the confidentiality of human genetic data** linked to an identifiable person, a family or, where appropriate, a group, in accordance with domestic law consistent with the international law of human rights.

--Article 14 (a)

VII.Ethically- and legally-valid * disclosures of Health Information (1)

1.De-identified Health Information

e.g.,coded information

2.Publicly-available health information

e.g., those in published research

3. Mandatory Reporting Laws

e.g.,

- ☞ RA 3573 (Philippine Law on Reporting of Communicable Diseases)
  e.g., SARS, dengue

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*varies from country to country

VII. Ethically and legally-valid disclosures of Health Information (2)

- 5.Judicial and administrative proceedings *

  e.g.,subpoena *duces tecum/ ad testificandum*

  - *In re Grand Jury Subpoena Dated Jan. 4, 1984*(1984)

    American PhD student's dissertation notes were subpoenaed by a federal jury in relation to arson

  - Application of J. R. Reynolds Tobacco Company (1987)

    American tobacco company sought *duces tecum* of tobacco-related health research data for its defense against a tobacco-related cancer complaint

6. Law enforcement activities

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depends on judicial set-up

VIII.Responsibilities of Researchers and Ethics Review Committees (1)

1. Just as the protection program (scientific, ethical and regulatory review)should ensure that risks in the study are minimized and participants' safety is assured, **it should also take precautions to protect the privacy and confidentiality of participants during and after the study .**

2.If research requires the use/disclosure of identifiable information, **researchers must get the consent of participants and approval of the ethics review committee.**

VIII. Responsibilities of Researchers and Ethics Review Committees (2)

3. Researcher's obtaining of consent for the use of participant's identifiable health information must be **included in the main consent form.**

4. The ERC reviewing the protocol asking for use/disclosure of identifiable health information must ensure that the use/disclosure **involves no more than minimal risk** to the privacy of individuals based on at least the presence of:

   (1) **an adequate plan presented to the ERC** to protect health information identifiers from improper use or disclosure;

VIII.Responsibilities of Researchers and Ethics Review Committees (3)

(2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law, and

adequate and formal written assurance that the identifiable health information will not be reused/disclosed to any person or entity except

(a) as required by law, or

(b)for authorized oversight of the research study; and

VIII.Responsibilities of Researchers and Ethics Review Committees (3)

(3) The research **could not practicably be conducted without access to and use of the identifiable health information.**

-- (Declaration of Helsinki, CIOMS Guidelines, ICH-GCP,International Declaration on Human Genetic Data, WHO Operational Guidelines)