Research Involving Human Subjects

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วิจัย

- หมายถึง การศึกษาค้นคว้าหาความรู้ ความจริง
  - อย่างเป็นระบบ ตามระเบียบแบบแผนและวิธีการวิจัย
  - เพื่อให้ได้มาซึ่งองค์ความรู้ใหม่ หรือได้ข้อค้นพบใหม่ หรือแนวปฏิบัติใหม่
    - ใช้แก้ปัญหา ปรับปรุงและพัฒนากิจกรรมต่างๆ
    - นำไปตั้งกฎ ทฤษฎี ที่อธิบายปรากฏการณ์ต่างๆ ได้อย่างน่าเชื่อถือ

จรรยาวิชาชีพวิจัยและแนวปฏิบัติ สำนักงานคณะกรรมการวิจัยแห่งชาติ, 2555

งานวิจัยที่เกี่ยวข้องกับมนุษย์

- กระบวนการศึกษา....
  - ที่กระทำต่อร่างกายหรือจิตใจของอาสาสมัคร หรือ
  - ที่กระทำต่อ cell, cell component, biospecimens, genetic materials medical records หรือ health information
  - และ รวมถึงการศึกษาทางสังคมศาสตร์ พฤติกรรมศาสตร์ และมนุษยศาสตร์ ที่เกี่ยวข้องกับสุขภาพ

จริยธรรมการวิจัยในคน สำนักงานคณะกรรมการวิจัยแห่งชาติ

งานวิจัยที่เกี่ยวข้องกับมนุษย์

- ก่อนเริ่มดำเนินการวิจัย .....ต้องผ่านการทบทวนพิจารณาและอนุมัติหรือเห็นชอบ จากคณะกรรมการจริยธรรมการวิจัยในคน

แนวทางจริยธรรมการทำวิจัยในคนในประเทศไทย 2550, FERCIT

The Belmont Report

- February 1976
- Basic ethical principles for biomedical and behavioral research involving human subjects
- 3 parts
  - Boundaries between practice and research
  - Basic ethical principles
  - Applications

OHRP , 2018

I. Practice & Research

- Practice: designed solely for individual patients
- Research: generalizable knowledge

OHRP , 2018

II. Basic Ethical Principles

- Respect for persons
- Beneficence
- Justice

OHRP , 2018

Respect for persons

- Individuals should be treated as autonomous agents.
- Persons with diminished autonomy are entitled to protection.

OHRP , 2018

Beneficence

- Do not harm
- Maximize possible benefits and minimize possible harms

OHRP , 2018

Justice

- Who ought to receive the benefits of research and bear its burdens?
- Fairness in distribution

OHRP , 2018

III. Applications

- Respect for persons → Informed Consent
- Beneficence → Assessments of risks and benefits
- Justice → Selection of subjects

OHRP , 2018

Informed Consent

- 3 elements
  - Information
  - Comprehension
  - Voluntariness

OHRP , 2018

Informed Consent (Information)

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

OHRP , 2018

Informed Consent (Information)

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

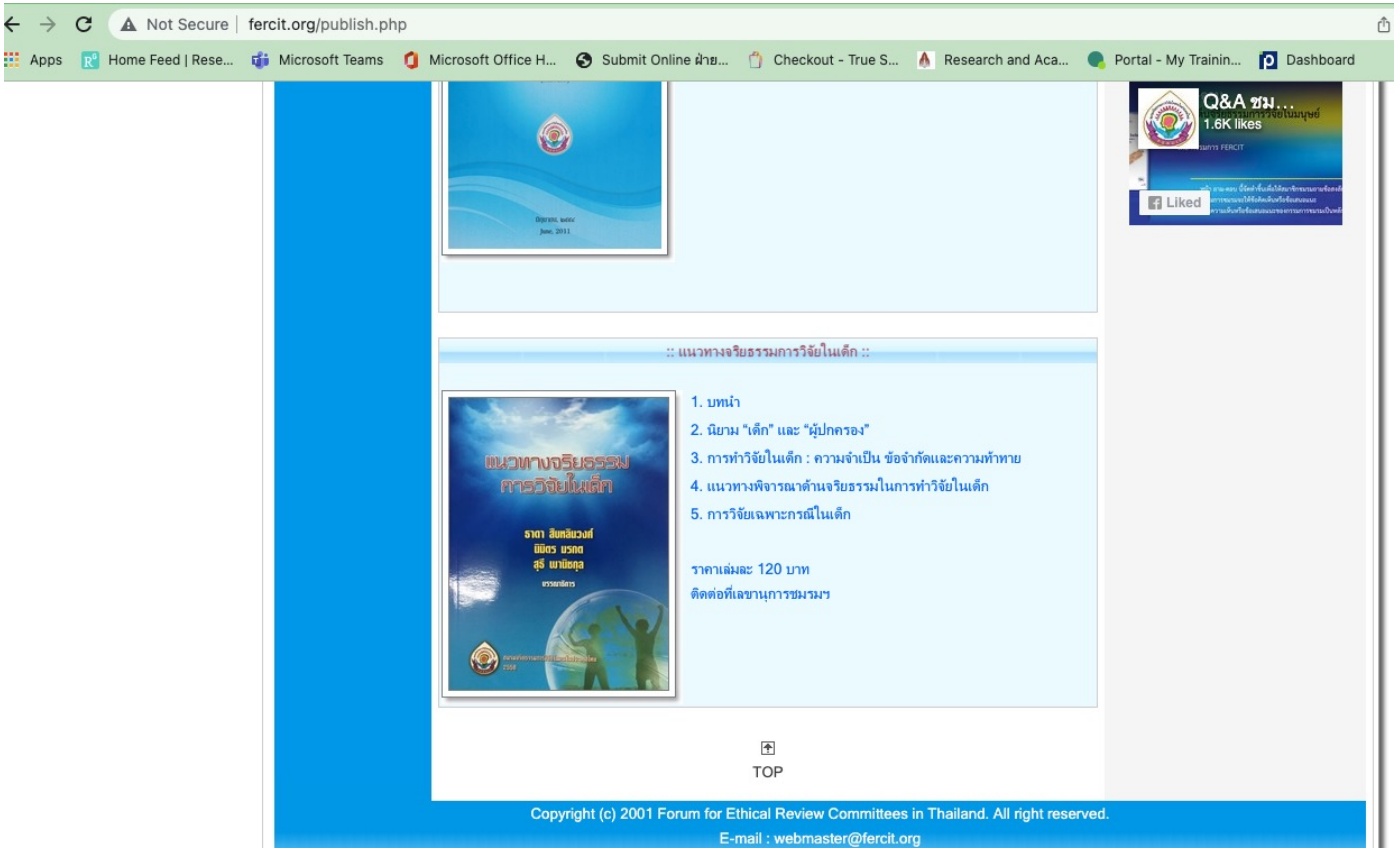
OHRP , 2018

Informed Consent (Comprehension)

- Manner and context to convey information
- Ability to understand is a function of intelligence, rationality, maturity and language.
- Investigators' obligations to ascertain subject's comprehension.
- When where and how to obtain informed consent are important.
- Special provision required when comprehension is severely limited.

OHRP , 2018

Informed Consent (Comprehension)



Informed Consent (Voluntariness)

- Valid consent only if voluntarily given.
- Required free of coercion and undue influence
- Who obtained informed consent is important.

OHRP , 2018

III. Applications

- Respect for persons → Informed Consent
- Beneficence → Assessments of risks and benefits
- Justice → Selection of subjects

OHRP , 2018

Assessment of risks and benefits

- Investigator - examine whether the research is properly designed
- EC – determine whether the risks to subjects are justified
- Subjects –determine whether or not to participate

OHRP , 2018

Assessment of risks and benefits

- Risk - possibility that harm may occur (chance and magnitude)
  - psychological, physical, legal social and economic harm
- Benefit – positive value related to health/welfare

OHRP , 2018

Assessment of risks and benefits

- Assessment of justifiability of research
  - Brutal/ inhumane treatment is never morally justified.
  - Risks should be reduced to those necessary to achieve the research objectives.
  - If research involves significant risk of serious impairment, extraordinarily on the justification of risk must be emphasis.
  - The appropriateness of involving vulnerable populations in research should be demonstrated.

OHRP , 2018

Assessment of risks and benefits

- Assessment of justifiability of research
  - Relevant risks and benefits must be thoroughly arrayed in documents including informed consent.

OHRP , 2018

III. Applications

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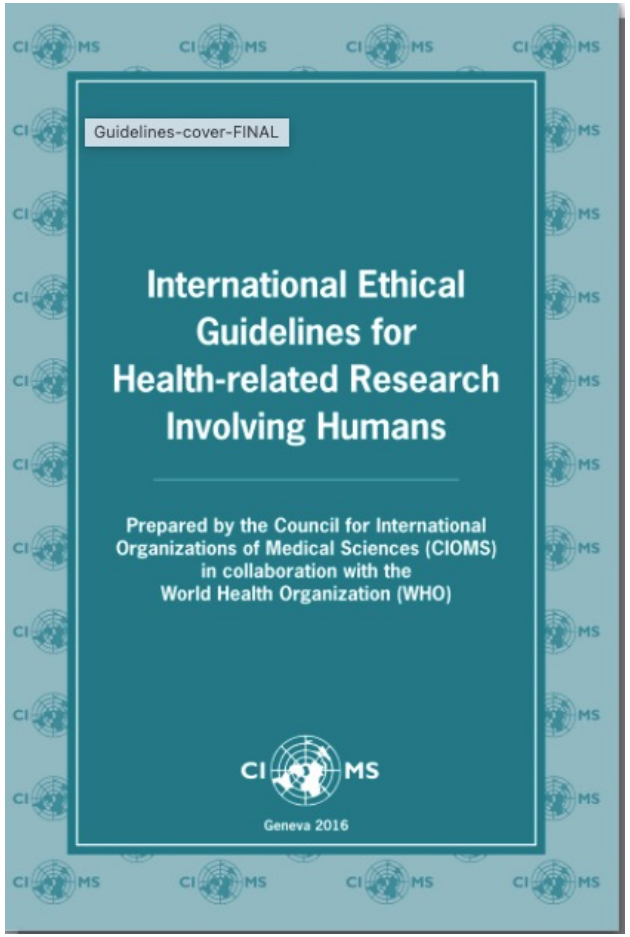
OHRP , 2018

Selection of Subjects

- Fair procedures and outcomes in the selection of research subject
- 2 level: social and individual levels

OHRP , 2018

Further Resources



CIOMS 2016

CIOMS 2016

Continuing report

- Renew/ progress report
- Amendment
- SAEs and safety report
- Protocol noncompliance/ deviation/ violation
- Closing report

ICH-GCP

For questions or comments

- pantipawongwai@gmail.com
- FERCIT website (Q&A)