

Introduction to Research Ethics & GCP

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การวิจัยในมนุษย์

Research Involving Human Subjects / Human Research

Definition of Research

“A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**”

(Ref. 32 CFR 219.102.d)

Definition of Research

“A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**”

(Ref. 32 CFR 219.102.d)

- **Systematic investigation** (การศึกษาอย่างเป็นระบบหรือมีหลักเกณฑ์)
- “A **predetermined method** for answering certain questions or studying a specific program or topic”
- **Scientific method**

Definition of Research

“A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**”

§ 32 CFR 219.102.d)

- Information collected can be applied beyond a particular program,
- Not considered generalizable knowledge, if the information is used only for:
 - a) internal improvements to a program or service.
 - b) quality assurance purposes

Definition of Research

“A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**”

§ 32 CFR 219.102.d)

- **External validity:**
 - **Generalizability** in quantitative research
 - **Transferability** in qualitative research

Definition of Research Involving Human Subjects

- Relate to human subjects including healthy volunteers
- Cannot be considered as an element of accepted clinical management or public health practice

(Ref. World Health Organization, Governance, rules and procedures, WHO Manual XVII)

Definition of Research Involving Human Subjects

- And involve
 - physical or psychological intervention or
 - observation, or
 - collection, storage and dissemination of information relating to individuals

(Ref. World Health Organization, Governance, rules and procedures, WHO Manual XVII)

Definition of Research Involving Human Subjects

- Research in which environmental factors are manipulated in a way that could incidentally expose individuals to undue risks.

(Ref. World Health Organization, Governance, rules and procedures, WHO Manual XVII)

Definition of Research Involving Human Subjects

- Medical research involving human subjects, including research on identifiable human material and data

(Ref. Declaration of Helsinki, 2013)

Types of Medical Research

- Various classification/types of researches

I. Observational



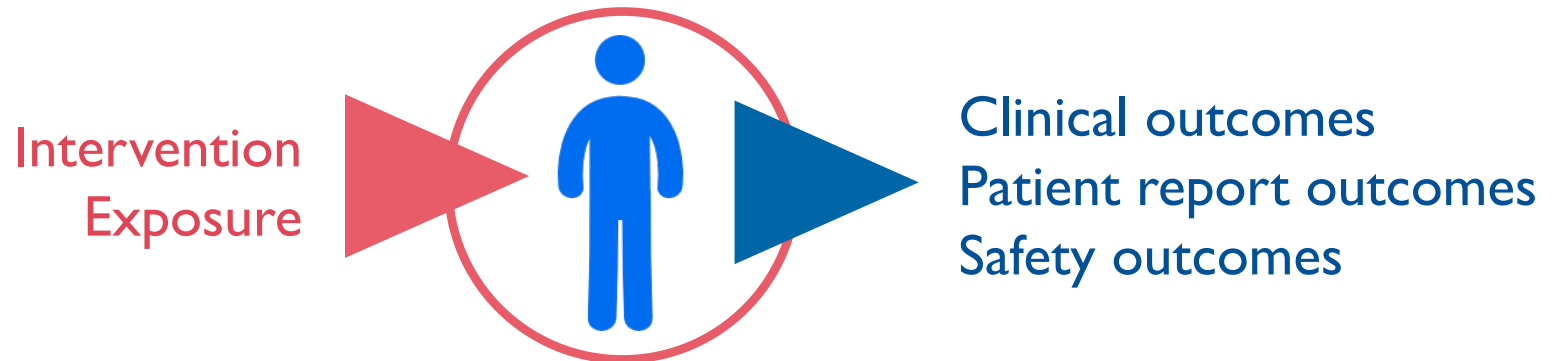
Characteristics, times, places
Risk factors
Predictive factors

- a. Cross-sectional,
- b. Longitudinal or prospective
- c. Retrospective
- d. Survey
- e. Descriptive
- f. Analytic: association, prediction

Types of Medical Research

- Various classification/types of researches

2. Experimental or interventional



- a. Investigational products: drug, vaccine, medical device
- b. Other medical intervention: rehabilitation, nursing care
- c. Psychological or behavioral intervention:
- d. Social intervention/program
- e. Traditional medicine or herbal product

Types of Medical/Healthcare Research

2. Experimental or interventional

- Drug or biological products
 - New drugs: investigational new drug (IND)
 - Phase 1 – 2 clinical trials: pharmacokinetics and pharmacodynamics, exposure-response, dose-ranging, exploratory study (proof of concept)
 - Phase 3 clinical trials: confirmatory studies
 - Marketed drugs:
 - Phase 4 clinical trial/study

Types of Medical/Healthcare Research

2. Experimental or interventional

- Medical devices:

- Screening or diagnostic test, treatment, rehabilitation,
- information technology
- Non-invasive vs. invasive device
- Exploratory and confirmatory clinical trial

Types of Medical/Healthcare Research

2. Experimental or interventional

- Other medical interventions e.g.,
 - Health promotion or health education
 - Self-care management, symptom management

Types of Medical/Healthcare Research

2. Experimental or interventional

- Other medical interventions e.g.,
 - Behavioral intervention e.g.
 - digital intervention,
 - social media,
 - cognitive-behavioral therapy
 - Social program e.g.
 - to reduce social inequality in health,
 - to improve neighbor and housing condition, to improve health conditions of childhood, minority or disease groups

Types of Medical/Healthcare Research

3. Others

- Action research
- Community participatory research

Types of Medical/Healthcare Research

I. Quantitative research

- Objectivity vs. subjectivity outcome
- Numerical analysis
- Inferential statistics

Types of Medical/Healthcare Research

2. Qualitative research

- Exploratory research
- Subjectivity (researcher is an integral part):
 - in-depth interview,
 - focus group method,
 - observation
- Textual analysis

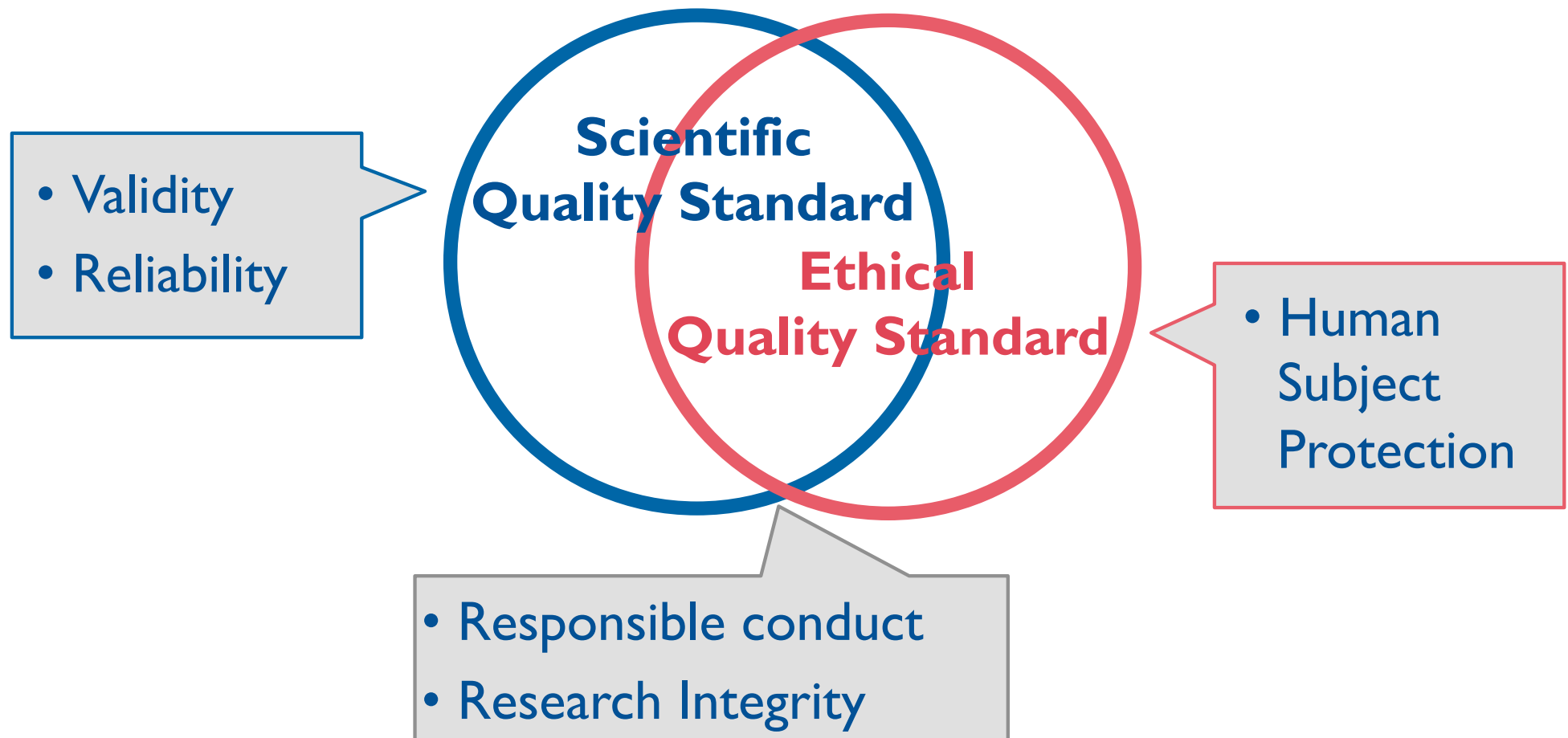
3. Mixed-method

มาตรฐานคุณภาพการวิจัย

ทางด้านวิทยาศาสตร์ และทางด้านจริยธรรม

Scientific & Ethical Quality Standard

Scientific & Ethical Quality Standard

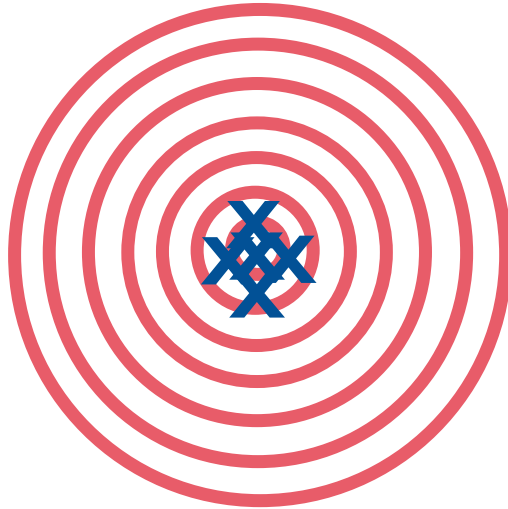


ดำเนินวิจัยอย่างรับผิดชอบ, ดำเนินการวิจัยครบถ้วน/สมบูรณ์/ถูกต้อง/เชื่อถือได้/ซื่อสัตย์สุจริต

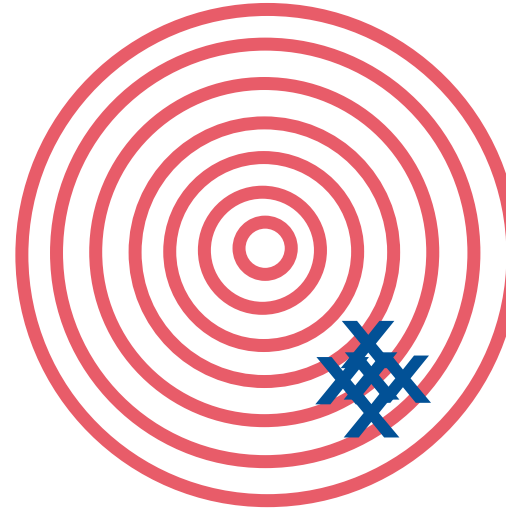
Scientific Quality Standard

Validity & Reliability

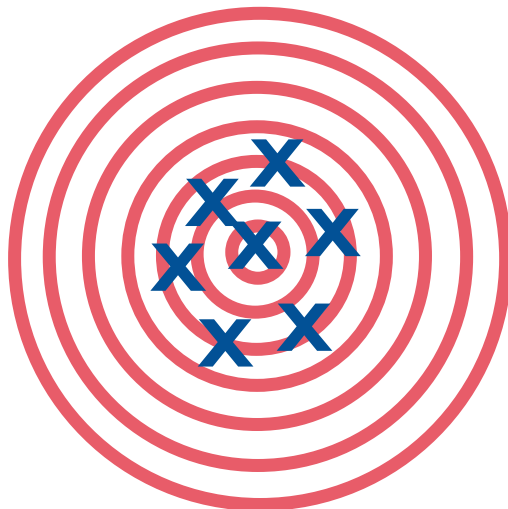
Valid
Reliable



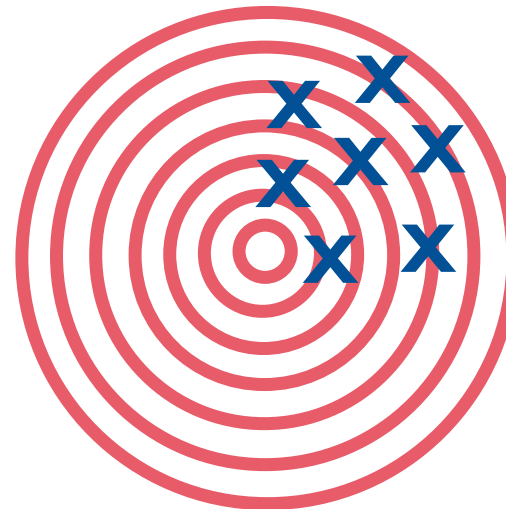
Not Valid
Reliable



Valid
Not Reliable



Not Valid
Not Reliable



Internal Validity

- Internal validity
 - The study results are true
 - Research question and objectives match
 - study design,
 - study population & setting,
 - exposure & outcome measurements
 - Protection against systemic bias/confounding, non-systemic bias
 - Statistical analysis and inferential error

Internal Validity

- Internal validity in quantitative research
 - Triangulation methods (data verification of data)
 - 1) Data triangulation
 - 2) Investigator triangulation
 - 3) Method triangulation
 - 4) Theoretical triangulation

External Validity

- External validity in quantitative research
 - **Generalizability**: study results can apply to the intended population
 - Inferential statistics
 - Study population and sampling
 - Sample size estimation and statistical power to detect meaningful effect and effect size

External Validity

- External validity in qualitative research
 - **Transferability**: study can transfer to other context

Reliability

- Reliability
 - **Repeatability**: if the research is repeated, the results are consistent (repeatability)
 - **Dependability**, in qualitative research
 - require clear description the framework used in data analysis and adequate description (thick description) of findings to support conclusion

Scientific Quality Standard

Most of all

- Honest
- Open mindedness
- Thorough reporting

Ethical Quality Standard

Ethical Quality Standard

- Honesty and integrity
- Objectivity (to avoid or minimize bias or self-deception)
- Carefulness
- Openness
- Respect for authorship and responsible publication
- Respect for intellectual property
- Respect for colleagues
- Responsible monitoring

Ethical Quality Standard

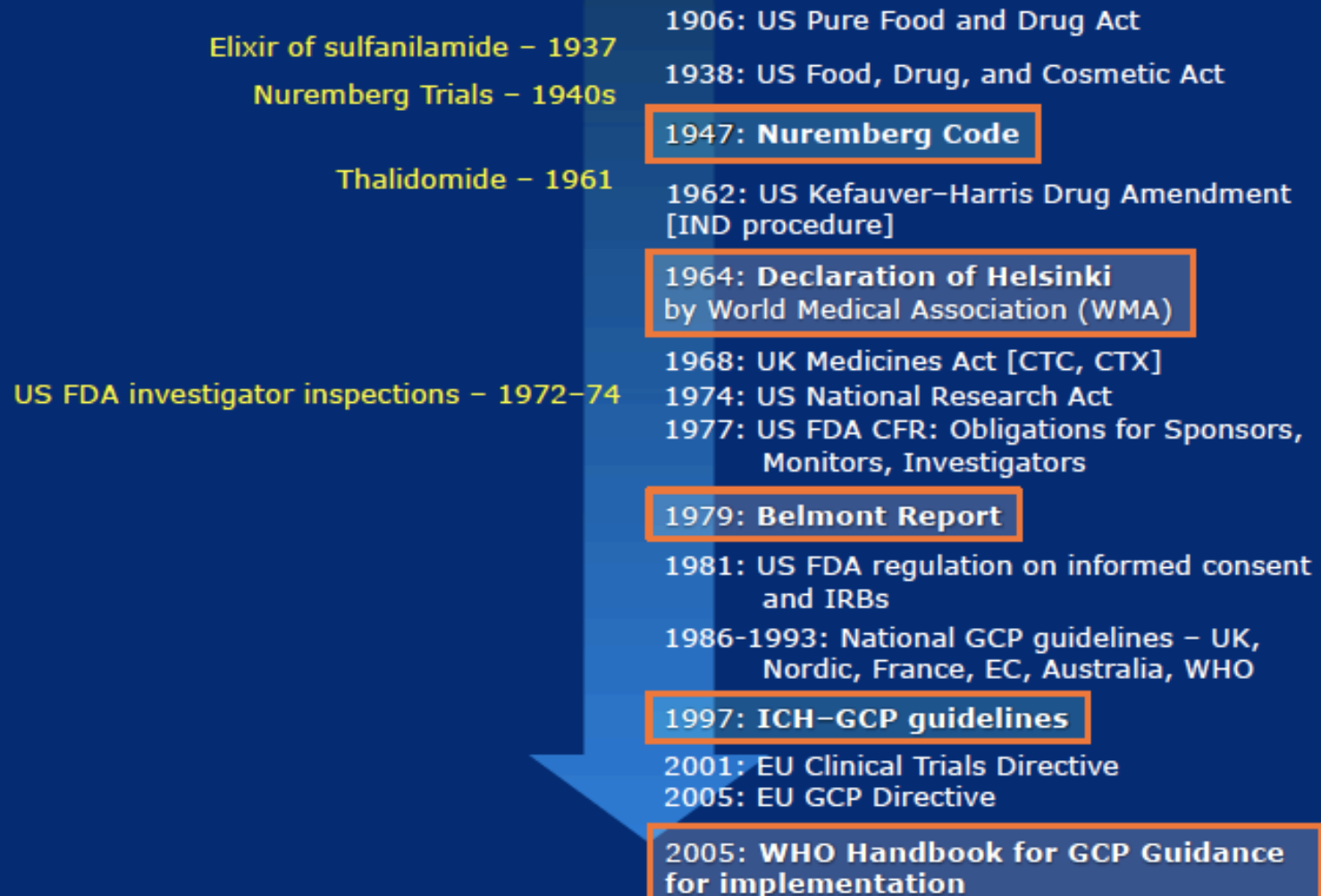
- Social responsibility
- Non-discrimination
- Competence
- Legality
- Animal care
- Protection of human subjects

(Ref. Resnik D.B., What is Ethics in Research & Why is it Important?, National Institute of Environmental Health Science, National Institute of Health, US, Department of Health and Human Services

Overview of Ethical Principles in Human Research

Development of Ethical Principles for Human Research & GCP Guidelines

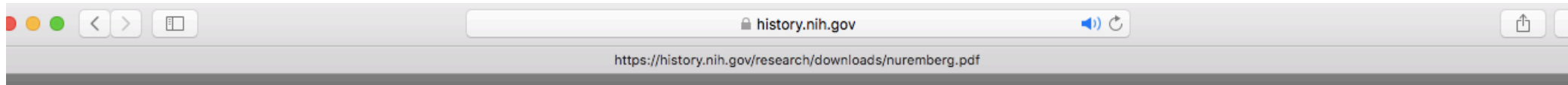
Development of Ethical Principles for human research and GCP guidelines



1947

NUREMBERG CODE

Nuremberg Code



THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each

Nuremberg Code

1. The voluntary consent of the human subject
2. Results should be fruitful and not be procurable by other methods
3. Experimental design should be based on the results of animal experimentation

Nuremberg Code

4. Avoid unnecessary physical and psychological suffering and injury
5. If the researcher believes that death or disabling injury may occur during the trial, the experiment should not be done
6. The degree of risk should not exceed the benefits of the experiment
7. Every possible action must be taken to protect the subject from injury, disability or death

Nuremberg Code

8. The experiment should be conducted by scientifically-qualified personnel
9. The subject may terminate the trial at any stage
10. The investigator must be prepared to terminate the trial at any stage

1964

DECLARATION OF HELSINKI

Declaration of Helsinki



The screenshot shows a web browser window with the URL wma.net. The page title is "WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association". The WMA logo is on the left, and a search bar and language selection (EN, ES, FR) are on the right. A "Join Us" button is also present. The navigation menu includes: WHAT WE DO, POLICY, PUBLICATIONS, NEWS & PRESS, WHO WE ARE, JUNIOR DOCTORS, and MEMBERS' AREA. The breadcrumb trail is: Policy / Current Policies / WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Social media icons for Facebook, Twitter, YouTube, and Email are shown, along with a font size selector (A- A+). The main heading is "WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS". A PDF icon is in the top right corner. The text states: "Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996". The date "29th March 2017" is in the top right. The "Policy Types" section lists "Declaration".

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association

WORLD MEDICAL ASSOCIATION

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WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

PDF

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:

- 29th WMA General Assembly, Tokyo, Japan, October 1975
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29th March 2017

Policy Types

Declaration

Declaration of Helsinki

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS



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48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002
(Note of Clarification added)

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

64th WMA General Assembly, Fortaleza, Brazil, October 2013

29th March 2017

Policy Types

Declaration

Tags

Clinical Study, Ethics, Ethics Committee, Helsinki, Human Subjects, Medical Research, Patient Autonomy, Placebo, Post-Trial Access, Principle, Publication, Register, Review Committee, Risk Assessment, Subject Protection, Vulnerable Populations

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Declaration of Helsinki

- A statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data

General Principles

- Physicians has duty to promote and protect health, well-being and rights of the research subjects
- Physicians has duty to protect the research subjects'
 - life and health
 - dignity and integrity
 - right to self-determination
 - privacy and confidentiality of personal information

General Principles

- The responsibility for the protection of research subjects must always rest with the physician or other health care professionals
 - Never rest with the research subjects, even though they have given consent.
 - Require knowledge and conscience.

Risks/Burdens and Benefits Assessment

- Medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the research subjects
 - May only be conducted if the importance of the objective (potential benefits) outweighs the risks and burdens to the research subjects
 - Measures to minimize the risks must be implemented

Investigators

- a) Has the appropriate ethics and scientific education, training and qualifications
- b) Initially and continuously assess risks and burden to research subjects in comparison with their benefit
- c) Implement measures to minimize the risks
- d) Must continuously monitor, assess and document the risks.
- e) Ensure appropriate compensation and treatment for subjects who are harmed as a result of participating in research

Vulnerable Subjects

- Justification in conduct of medical research in vulnerable subjects
 - a) the research is responsive to health needs or priorities of this group
 - b) the research cannot be conducted in non-vulnerable subjects
 - c) the study subject will get benefit from the results of the research

Research protocol

- a) Conform to scientific principles and principles in this Declaration
- b) Based on comprehensive review of scientific literatures, and adequate lab and animal experiments
- c) Clearly describe study design and method, ethical considerations, and post-trial provision
- d) Also include funding, sponsor, potential conflict of interest

Privacy and Confidentiality

- Every precaution must be taken to protect the confidentiality of personal information and the privacy of research subjects

Research Ethics Committee

- a) Must have transparent and independent function
- b) Must be appropriately qualified
- c) Must take into consideration the local laws and regulations and applicable international norms and standards
- d) Must have the right to monitor ongoing studies

Research Ethics Committee

- Researcher
 - a) must submit the protocol for review and approval
 - b) must provide monitoring information including serious adverse events
 - c) must submit protocol amendment for approval, if there is any
 - d) must submit a study final report after the end of the study

Informed consent

- Freely given informed consent is essential
- Attention in conduct of informed consent
 - preferably in writing
 - method in delivering the information
 - a dependent relationship with investigator

Informed consent

- Special attention and precaution
 - A. In subjects who are capable of giving informed consent
 - must be voluntary and freely agreed,
 - adequately informed

Informed consent

- Special attention and precaution
 - B. In subject who are incapable/ physically or mentally incapable of giving informed consent
 - Justification
 - Seeking informed consent from the legally authorized representative (LAR) and
 - Seeking assent from subject, if subject can make dissent
 - If LAR is not available and research cannot be delayed

Informed consent

- Special attention and precaution
 - C. In research on material or data contained in biobanks or similar repositories
 - If informed consent cannot be in written (non-written consent)

Disclosure of medical research involving human subjects

- Research registration and publication and dissemination of results
 - every research must be registered in a publicly accessible database before recruitment of the first subject
 - make publicly available the results of the research

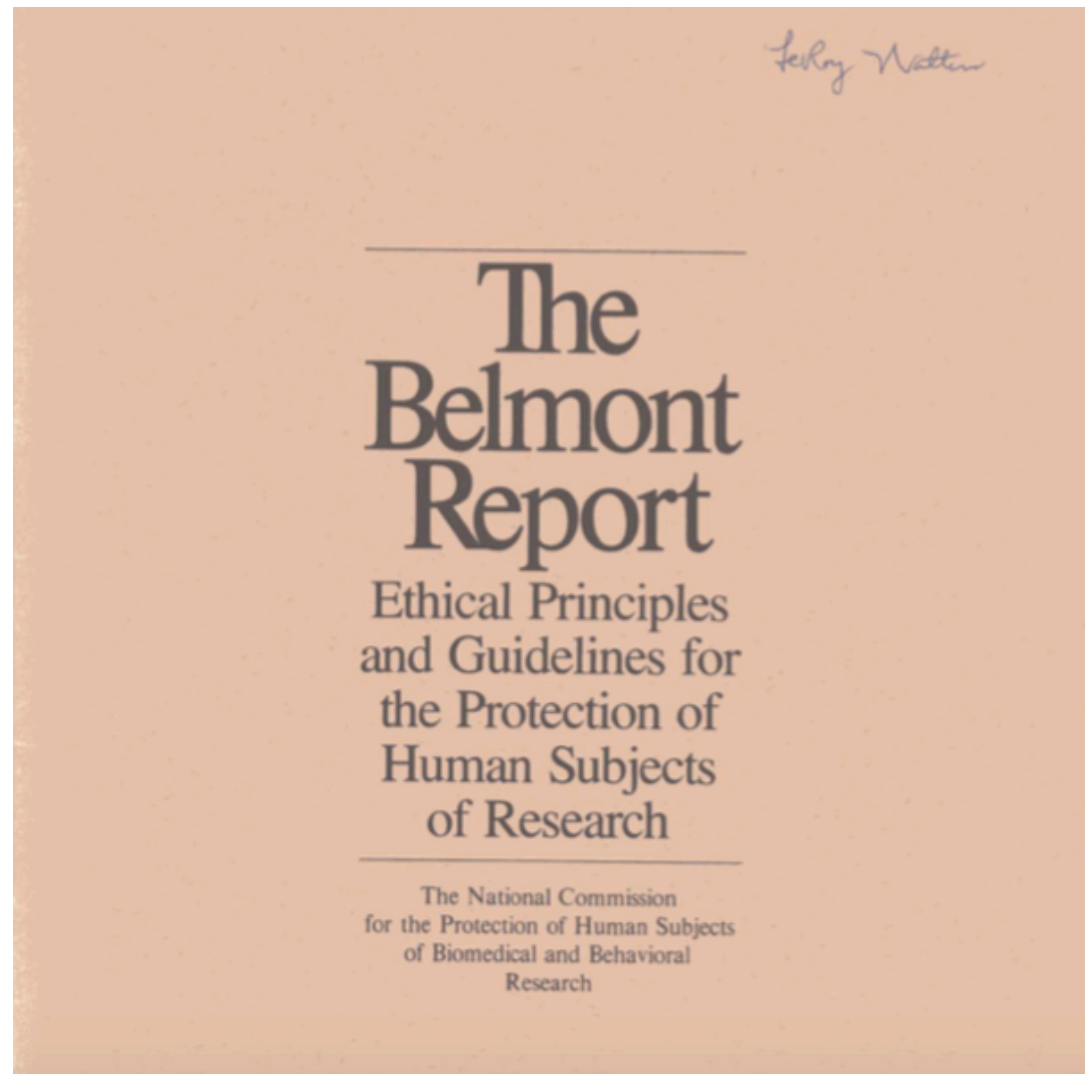
Others

- Use of placebo
- Post-Trial Provisions
 - In advance of a clinical trial, sponsors, researchers and host country governments
 - should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.
 - must also disclosed this information to participants during the informed consent process.
- Unproven Interventions in Clinical Practice

1979

BELMONT REPORT

Belmont Report



Belmont Report

hhs.gov

The Belmont Report | HHS.gov

HHS.gov U.S. Department of Health & Human Services
Office for Human Research Protections

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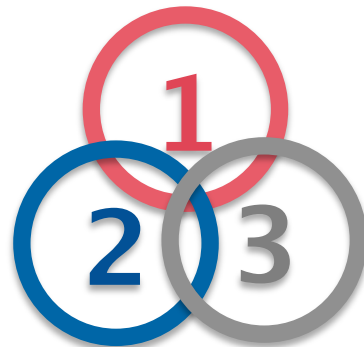
THE BELMONT REPORT
Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Belmont Report

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, US
- Ethical principles for the protection of human subjects of research
- Distinction between practice and research

Belmont Report

- 3 ethical principles
 - ① Respect for persons (หลักการเคารพบุคคล)
 - ② Beneficence and non-maleficence (หลักการคำนึงถึงประโยชน์ และไม่ทำอันตราย)
 - ③ Justice (distributive justice) (หลักความยุติธรรม)



Respect for Person

- A. Autonomy (self-determination, self-government)
ความเป็นอิสระ มีสิทธิในการตัดสินใจ และบริหารจัดการ
ตนเอง
- B. Confidentiality
การรักษาความลับข้อมูลส่วนตัว หรือความเป็นส่วนตัว

Application of Autonomy in Research

- Informed Consent
- Essential elements of Informed consent
 - ① Information
ข้อมูลเพื่อใช้ในการตัดสินใจ
 - ② Comprehension
ความสามารถในการเข้าใจข้อมูล
 - ③ Voluntariness
ความสมัครใจ ตัดสินด้วยตนเองโดยอิสระ

Application of Autonomy in Research

① Information

- ข้อมูลถูกต้อง เพียงพอ และครอบคลุมทุกด้าน

Application of Autonomy in Research

② Comprehension ความสามารถในการเข้าใจ

a. How information is conveyed

- manner and context วิธีการให้ข้อมูล สถานที่ และสิ่งแวดล้อม

b. Subject's ability to understand

- Intelligence สติปัญญา
- Rationality การประมวลเหตุผล
- Maturity ความเป็นผู้ใหญ่
- Language ภาษาเขียน และพูดอธิบาย

Application of Autonomy in Research

③ Voluntariness

- ความสมัครใจ หรือการตัดสินใจด้วยตนเองโดยอิสระ ปราศจาก
 - a. Coercion (physical & psychological) การบังคับ
 - b. Inducement การชักจูง โน้มน้าวที่ไม่เหมาะสม
 - c. Undue influence

Application of Beneficence in Research

- Assessment of Risks and Benefits
การประเมินประโยชน์ และ
การประเมินความเสี่ยงอันตรายของการวิจัย

Risk Assessment for Research



Risk Assessment for Research



Risk Assessment for Research



Potential risks in social & behavioral research

- Consequences of breach of confidentiality and privacy
- Embarrassment or upset from question about sexual or sensitive behaviors, beliefs, violations in family
- Stigmatizing
- Loss of reputation
- Loss of employment
- Civil or criminal penalty

Risk Assessment for Research



Study interventions

1. Drug
2. Medical device
3. Behavioral intervention
4. Social intervention

Terms

- Adverse events
- Unanticipated events

Risk Assessment for Research



Study interventions

1. Drug
2. Medical device
3. Behavioral intervention
4. Social intervention

Causes

- Side effect or Adverse drug reaction
- Interaction with concomitant treatment
- Overdose/overexposure or abuse
- Ineffective
- Quality defects

Risk Assessment for Research



Study Design

- Washout period
 - Screening period
 - Follow-up period during study & after study completion
 - Study population: selection criteria & recruitment process
- Discontinuation criteria (Stopping rules)
 - Rescue medications or treatments

Risk Assessment for Research



Study methods/procedures

- Diagnostic tests
- Outcome assessment tools e.g. Questionnaire
- In-depth interview & focus group
- DECPTION

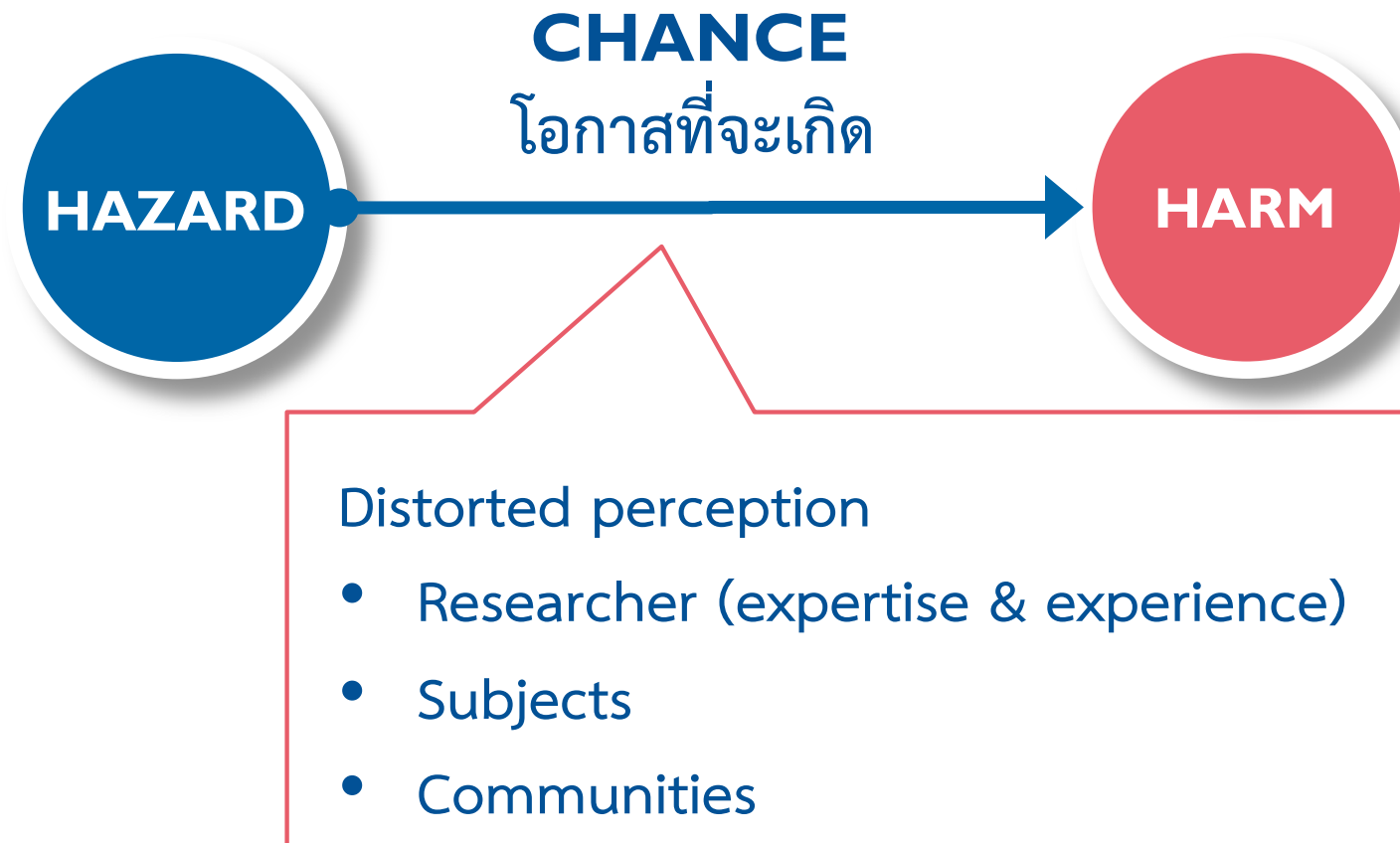
Risk Assessment for Research



Data collection & data analysis report

- Disclosure of confidential information

Risk Assessment for Research



Risk Assessment for Research



Researchers underestimate

IRB/IEC overestimate



Scientific value
Subjects/Community benefit

Risk Assessment for Research

- Classification of risks
 - ① Minimal risk
 - ② Minor increase over minimal risk
 - ③ Greater than minimal risk

“probability and magnitude of harm...are not greater...than

- those ordinarily encountered in daily life...
- during the performance of routine physical or psychological examinations or tests”

Ref. US 45CFR46

Risk Assessment for Research

- Classification of risks
 - ① Minimal risk
 - ② Minor increase over minimal risk
 - ③ Greater than minimal risk

Risks that is no more likely and not greater than that attached to routine medical or psychological examination

Ref. CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002

Benefit Assessment

- A. Potential benefits
- B. Direct benefit (to subjects)
- C. Indirect benefits

Application of Justice in Research

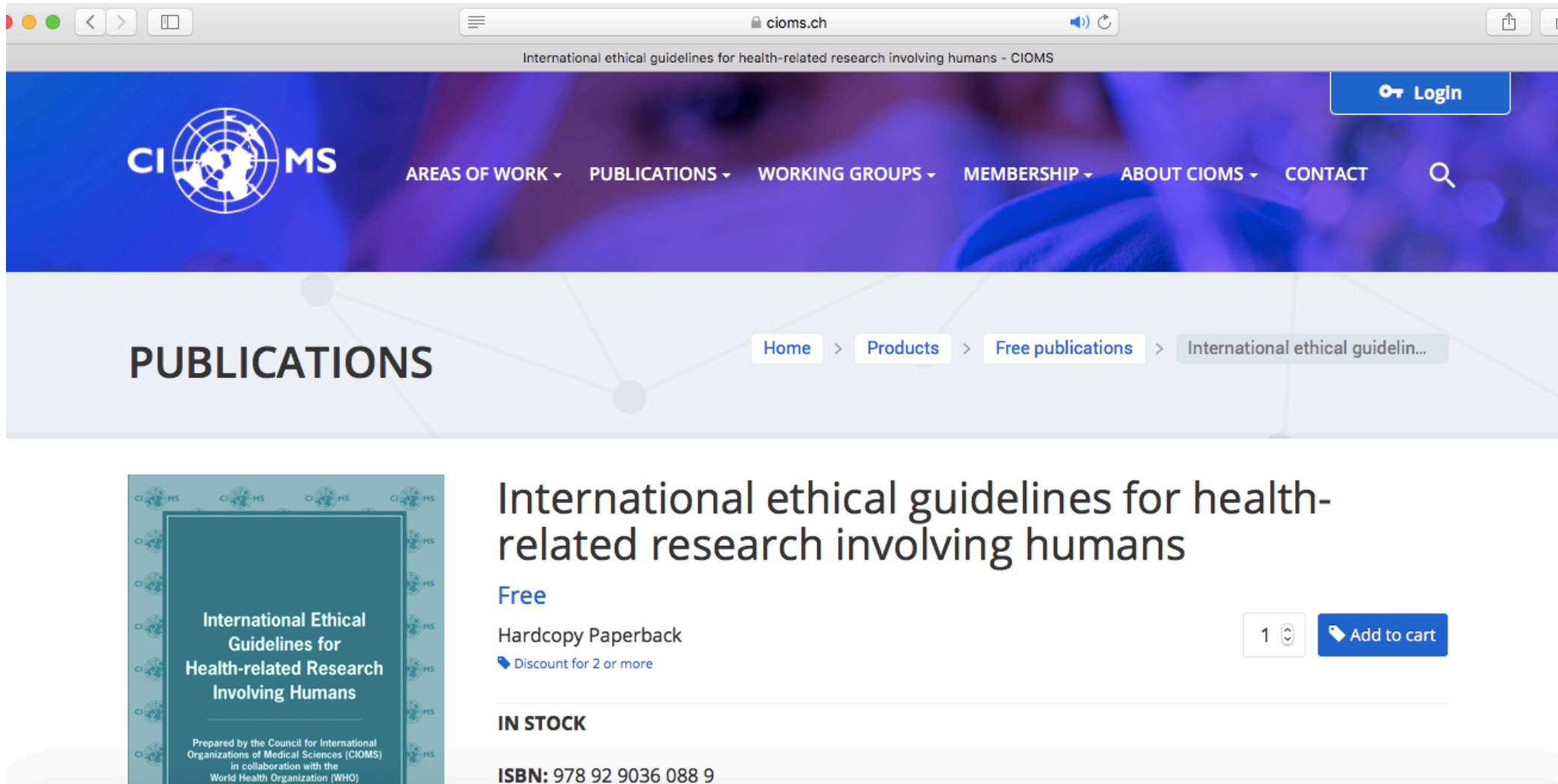
- Fair distribution of risks and benefits from research to whom?
 - Class of population
 - Community
 - Country
- Injustice may be from
 - Social. Institutionalized in the society
 - Racial
 - Sexual
 - Cultural biases

Application of Justice in Research

- Study population: selection criteria and sampling
- Study setting
- Study procedure
- Compensation
- Cost of trial related injuries

CIOMS ETHICAL GUIDELINES

CIOMS Ethical Guidelines



The screenshot displays the CIOMS website interface. At the top, a red banner features the title 'CIOMS Ethical Guidelines'. Below this, a browser window shows the website's header with the CIOMS logo, a navigation menu (AREAS OF WORK, PUBLICATIONS, WORKING GROUPS, MEMBERSHIP, ABOUT CIOMS, CONTACT), and a 'Login' button. The main content area is titled 'PUBLICATIONS' and includes a breadcrumb trail: Home > Products > Free publications > International ethical guidelin... The featured product is 'International ethical guidelines for health-related research involving humans', listed as 'Free' and available as a 'Hardcopy Paperback'. It includes a 'Discount for 2 or more' offer, a quantity selector set to '1', and an 'Add to cart' button. The product is marked 'IN STOCK' with ISBN: 978 92 9036 088 9. A small image of the book cover is shown on the left.

CIOMS

AREAS OF WORK ▾ PUBLICATIONS ▾ WORKING GROUPS ▾ MEMBERSHIP ▾ ABOUT CIOMS ▾ CONTACT 🔍

Login

PUBLICATIONS

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International ethical guidelines for health-related research involving humans

Free

Hardcopy Paperback

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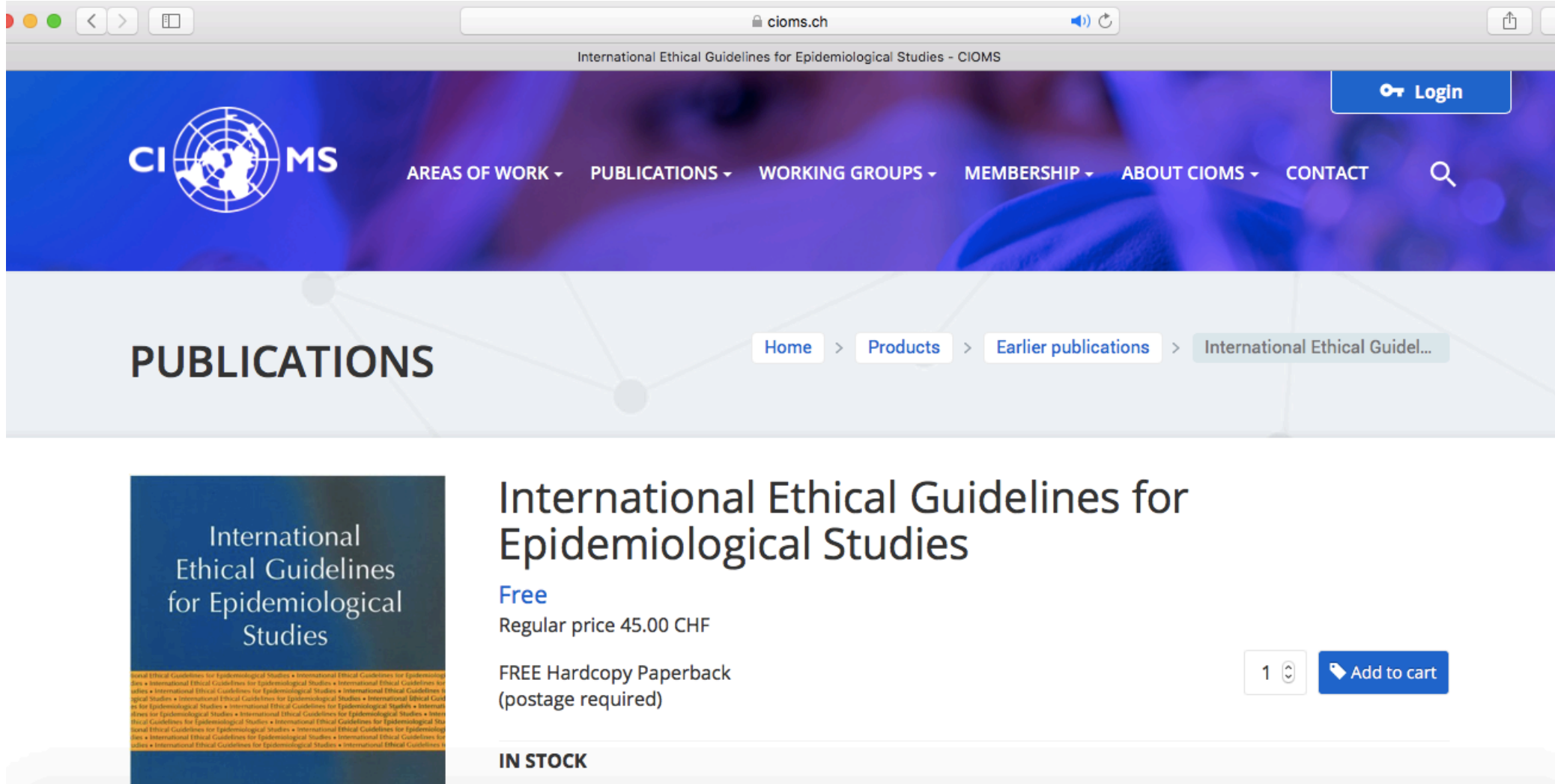
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ISBN: 978 92 9036 088 9

International Ethical Guidelines for Health-related Research Involving Humans

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)

CIOMS Ethical Guidelines



The screenshot shows a web browser window with the address bar displaying 'cioms.ch'. The page title is 'International Ethical Guidelines for Epidemiological Studies - CIOMS'. The navigation bar includes a 'Login' button and a menu with 'AREAS OF WORK', 'PUBLICATIONS', 'WORKING GROUPS', 'MEMBERSHIP', 'ABOUT CIOMS', and 'CONTACT'. A search icon is also present. The main content area is titled 'PUBLICATIONS' and features a breadcrumb trail: 'Home > Products > Earlier publications > International Ethical Guidel...'. The product being displayed is 'International Ethical Guidelines for Epidemiological Studies', which is available for free. The regular price is listed as 45.00 CHF. The product is described as a 'FREE Hardcopy Paperback (postage required)'. The quantity is set to 1, and there is an 'Add to cart' button. The status 'IN STOCK' is displayed at the bottom of the product section.

International Ethical Guidelines for Epidemiological Studies

Free

Regular price 45.00 CHF

FREE Hardcopy Paperback (postage required)

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GUIDELINES FOR GCP

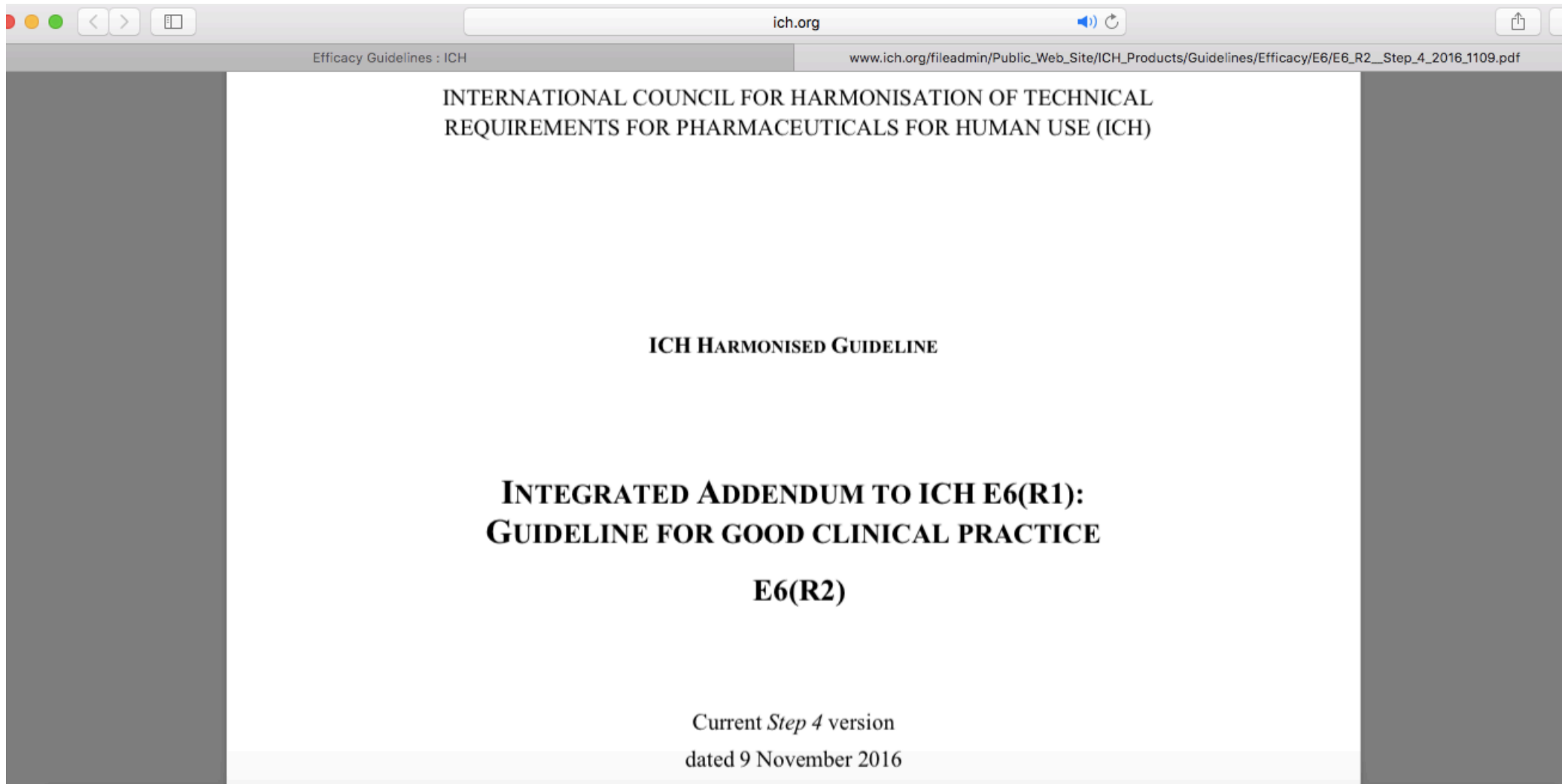
ICH E6 Guidelines for GCP

The screenshot shows the ICH website with the following elements:

- Header:** ICH logo with the tagline "harmonisation for better health". Navigation links include "Contact" and "Log In".
- Menu:** A horizontal bar with buttons for "Home", "About ICH", "Work Products" (highlighted), "Meetings", "Training", "Newsroom", and a search bar labeled "Search Our Site".
- Breadcrumbs:** "Efficacy Guidelines / ICH Guidelines / Work Products / Home".
- Text:** "The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/ pharmacogenomics techniques to produce better targeted medicines. [Zip file with all Efficacy Guidelines in Word format](#)".
- List of Guidelines:** A vertical list of dropdown menus for E1 through E6. E6 "Good Clinical Practice" is highlighted with a blue border.
- Table:** A table with three columns: "Code", "Document Title", and "Previously coded".

Code	Document Title	Previously coded
E1	Clinical Safety for Drugs used in Long-Term Treatment	
E2A - E2F	Pharmacovigilance	
E3	Clinical Study Reports	
E4	Dose-Response Studies	
E5	Ethnic Factors	
E6	Good Clinical Practice	

ICH E6 Guidelines for GCP



ICH E6 Guidelines for GCP

Introduction

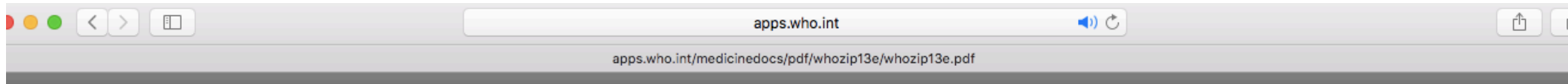
1. Glossary
2. The Principles of ICH GCP
3. Institutional Review Board/Independent Ethics Committee (IRB/IEC)
4. Investigator
5. Sponsor
6. Clinical Trial Protocol and Protocol Amendment(s)
7. Investigator's Brochure
8. Essential Documents for the Conduct of a Clinical Trial

1995 & 2005

WHO

GUIDELINES FOR GCP

WHO Guidelines for GCP



World Health Organization
WHO Technical Report Series, No. 850, 1995, Annex 3

**Guidelines for good clinical practice (GCP) for trials on
pharmaceutical products***

WHO Handbook for GCP: Guidance for Implementation

The image cannot be displayed. Your computer may not have enough memory to open the image, or the image may have been corrupted. Restart your computer, and then open the file again. If the red x still appears, you may have to delete the image and then insert it again.

Overview of GCP

Good Clinical Practice (GCP)		
Clinical Quality Assurance		
Protection	Safety	Data validation/ Quality control
Declaration of Helsinki	Adverse Events (AE) reporting	Protocol & Case Record Form
Regulatory approval		Site facilities & staff
IRB/IEC review		Monitoring, source data verification
Informed consent		Documentation, filing, archiving
		Drug accountability
		Data management & data analysis
		Report & publication
		Audit & inspection

ICH GCP vs Laws and Regulations

Clinical studies should be conducted in accordance with

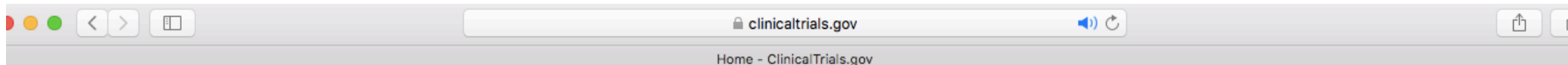
- 1) ICH GCP
- 2) Laws and regulations in countries of clinical trial conducted
- 3) Laws and regulations in countries of intended product registration

Law & Regulations in Thailand

- 1) Thai FDA Import permit,
- 2) National Health Act
- 3) Mental Health Act
- 4) Human Research Act: will it be issued?
- 5) Professional Associations' guidelines
- 6) Institution' s policy
- 7) Other related laws

Clinical Trial Disclosure

ClinicalTrials.gov



We updated the design of this site on December 18, 2017. [Learn more.](#)

NIH U.S. National Library of Medicine

ClinicalTrials.gov

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ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 263,863 research studies in all 50 states and in 202 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the risks and

Find a study (all fields optional)

Recruitment status ⓘ

- ☐ Recruiting and not yet recruiting studies
- ☒ All studies

Condition or disease ⓘ (For example: breast cancer)

X

Other terms ⓘ (For example: NOT number drug name, investigator name)

WHO International Clinical Trials Registry Platform (ICTRP)

The screenshot shows the WHO ICTRP website interface. At the top, there's a blue banner with the title 'WHO International Clinical Trials Registry Platform (ICTRP)'. Below this, the website header includes the WHO logo, the text 'World Health Organization', and a navigation bar with links for Health topics, Data, Media centre, Publications, Countries, Programmes (highlighted), Governance, and About WHO. A search bar is also present. The main content area is titled 'International Clinical Trials Registry Platform (ICTRP)' and features a 'Welcome to the WHO ICTRP' section. This section includes a paragraph about the mission of the platform, a photograph of a group of people, and a quote: 'The registration of all interventional trials is a scientific, ethical and moral responsibility.' Below this, there's a 'What is a clinical trial?' section. On the left side, there's a sidebar with a list of links: International Clinical Trials Registry Platform, About, Registry Network, Search portal, Unambiguous trial identification, Reporting of findings, News and events, Publications, and Clinical trials in children. On the right side, there's a large blue cross logo with 'ICTRP' inside, and a 'Search for Trials' section with links for 'List By Health Topics', 'List By Countries', and 'List By Regions/Countries'.

WHO | Welcome to the WHO ICTRP

Sign up for WHO updates

WHO | World Health Organization

عربي 中文 English Français Русский Español

Health topics Data Media centre Publications Countries **Programmes** Governance About WHO

Search

International Clinical Trials Registry Platform (ICTRP)

Welcome to the WHO ICTRP

The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

The registration of all interventional trials is a scientific, ethical and moral responsibility.

What is a clinical trial?

For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

WHO/P. Viot

Search for Trials

List By Health Topics

List By Countries

List By Regions/Countries

WHO International Clinical Trials Registry Platform (ICTRP)

WHO | Primary Registries

Sign up for WHO updates

International Clinical Trials Registry Platform

About

Registry Network

Search portal

Unambiguous trial identification

Reporting of findings

News and events

Publications

Clinical trials in children

Primary Registries

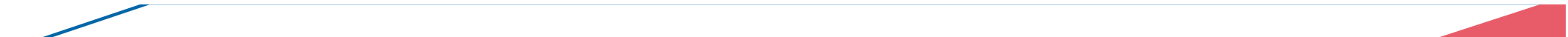
[WHO Registry Criteria](#) | [WHO Data Set](#) | [Primary Registries](#) | [Partner Registries](#)

Primary Registries in the WHO Registry Network

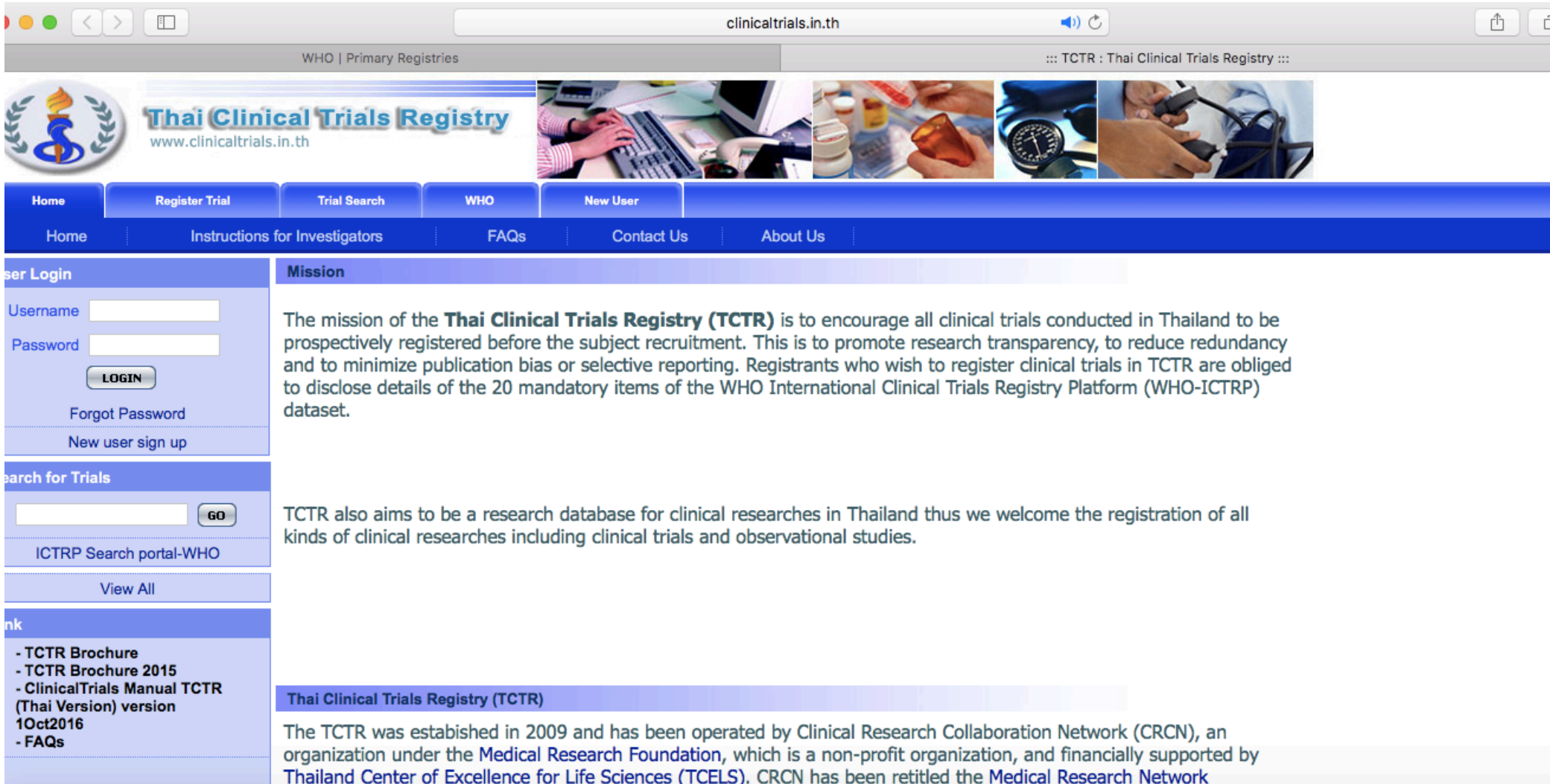
Primary Registries in the WHO Registry Network meet [specific criteria](#) for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE.

The registries that currently meet these criteria are:

Australian New Zealand Clinical Trials Registry (ANZCTR)	Profile	Website
Brazilian Clinical Trials Registry (ReBec)	Profile	Website
Chinese Clinical Trial Registry (ChiCTR)	Profile	Website
Clinical Research Information Service (CRiS), Republic of Korea	Profile	Website
Clinical Trials Registry - India (CTRI)	Profile	Website
Cuban Public Registry of Clinical Trials (RPCEC)	Profile	Website
EU Clinical Trials Register (EU-CTR)	Profile	Website
German Clinical Trials Register (DRKS)	Profile	Website
Iranian Registry of Clinical Trials (IRCT)	Profile	Website
ISRCTN	Profile	Website
Japan Primary Registries Network (JPRN)	Profile	Website (in Japanese)
		Network members:
		UMIN CTR
		Website
		JapicCTI Website
		JMACCT CTR
		Website
Thai Clinical Trials Registry (TCTR)	Profile	Website
The Netherlands National Trial Register (NTR)	Profile	Website
Pan African Clinical Trial Registry (PACTR)	Profile	Website
Peruvian Clinical Trial Registry (REPEC)	Profile	Website
Sri Lanka Clinical Trials Registry (SLCTR)	Profile	Website



Thai Clinical Trials Registry (TCTR)



Question & Discussion