MAHIDOL UNIVERSITY
Wisdom of the Land

Roles & Responsibilities of Investigator & IRB

Jaranit Kaewkungwal

ORS – FTM-EC

Mahidol University

Regulatory & Guidelines

CDISC Strength Through Collaboration

CDASH

CDASH

United States Department of Health & Human Services

U.S. Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

SCDM

CDER Handbook

OFFICE OF HUMAN SUBJECTS RESEARCH

Regulatory & Guidelines

GCP & Computer / Database Management Systems

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- The European Agency for the Evaluation of Medicinal Products (EMEA)
- FDA Center for Drug Evaluation and Research (CDER)
- Human Subject Protections- Office of Human Subjects Research, NIH (OHSR)
- WORLD MEDICAL ASSOCIATION
- Standard operating procedures for clinical investigators (WHO GCP SOP)

GCP & Computer / Database Management Systems

TABLE 2.—LIST OF RELEVANT ICH GUIDANCES AND TOPICS

Code	Topic
E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions
E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
E2B	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
E2C	Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
E3	Structure and Content of Clinical Study Reports
E4	Dose-Response Information to Support Drug Registration
E5	Ethnic Factors in the Acceptability of Foreign Clinical Data
E6	Good Clinical Practice: Consolidated Guideline
E7	Studies in Support of Special Populations: Geriatrics
E8	General Considerations for Clinical Trials
E9	Statistical Considerations in the Design of Clinical Trials
E10	Choice of Control Group in Clinical Trials
M3	Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
S6	Safety Studies for Biotechnology-Derived Products

MAHIDOL UNIVERSITY
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ICH & GCP Guidance

ORS
FTM-EC

1996

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE
E6(R1)

Current *Step 4* version
dated 10 June 1996

(including the Post Step 4 corrections)

This Guideline has been developed by the appropriate ICH Expert Wor
has been subject to consultation by the regulatory parties, in accordan
Process. At Step 4 of the Process the final draft is recommended for
regulatory bodies of the European Union, Japan and USA.

emea European Medicines Agency

July 2002
CPMP/ICH/135/95

ICH Topic E 6 (R1)
Guideline for Good Clinical Practice

Step 5

NOTE FOR GUIDANCE ON GOOD CLINICAL PRACTICE
(CPMP/ICH/135/95)

TRANSMISSION TO CPMP	July 1996
FINAL APPROVAL BY CPMP	July 1996
DATE FOR COMING INTO OPERATION	January 1997
POST STEP ERRATA (linguistic minor corrections)	July 2002

Guidance for Industry

E6 Good Clinical Practice: Consolidated Guidance

ICH
April 1996

ICH & GCP Guidance

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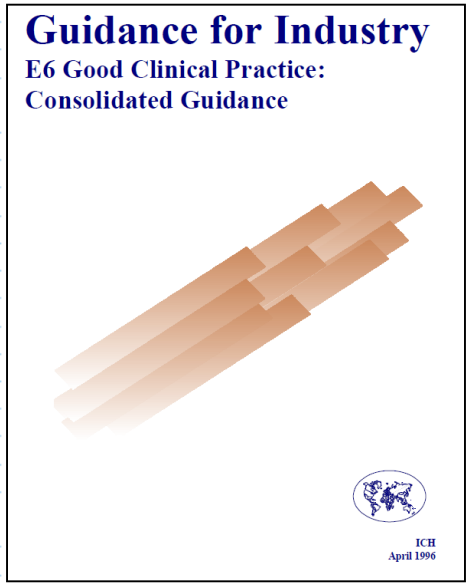
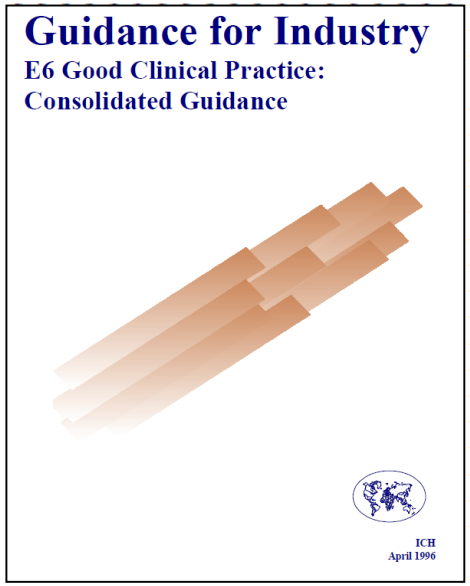


ICH & GCP Guidance



ICH & GCP Guidance

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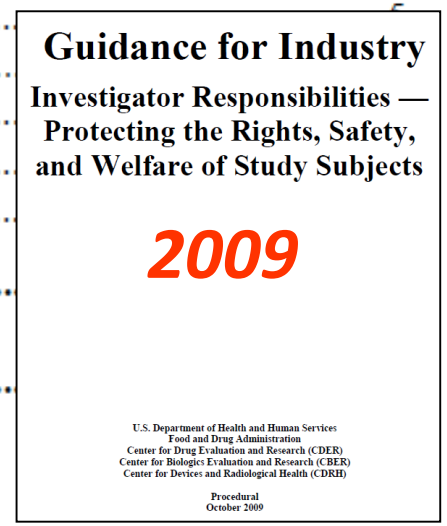

ICH & GCP Guidance

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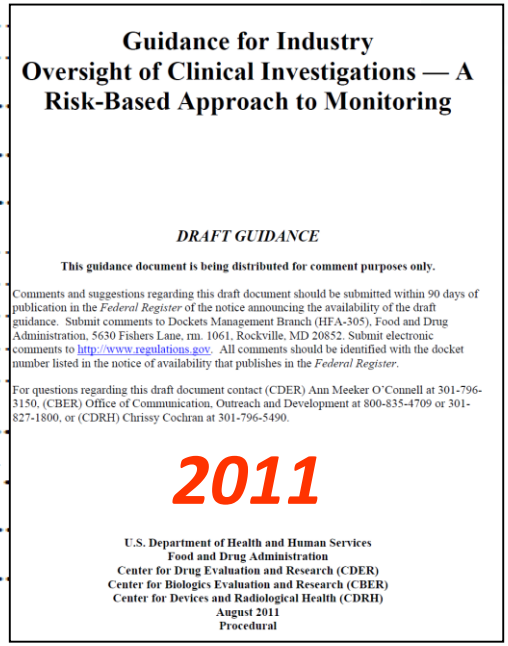


Guidance for Industry
Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

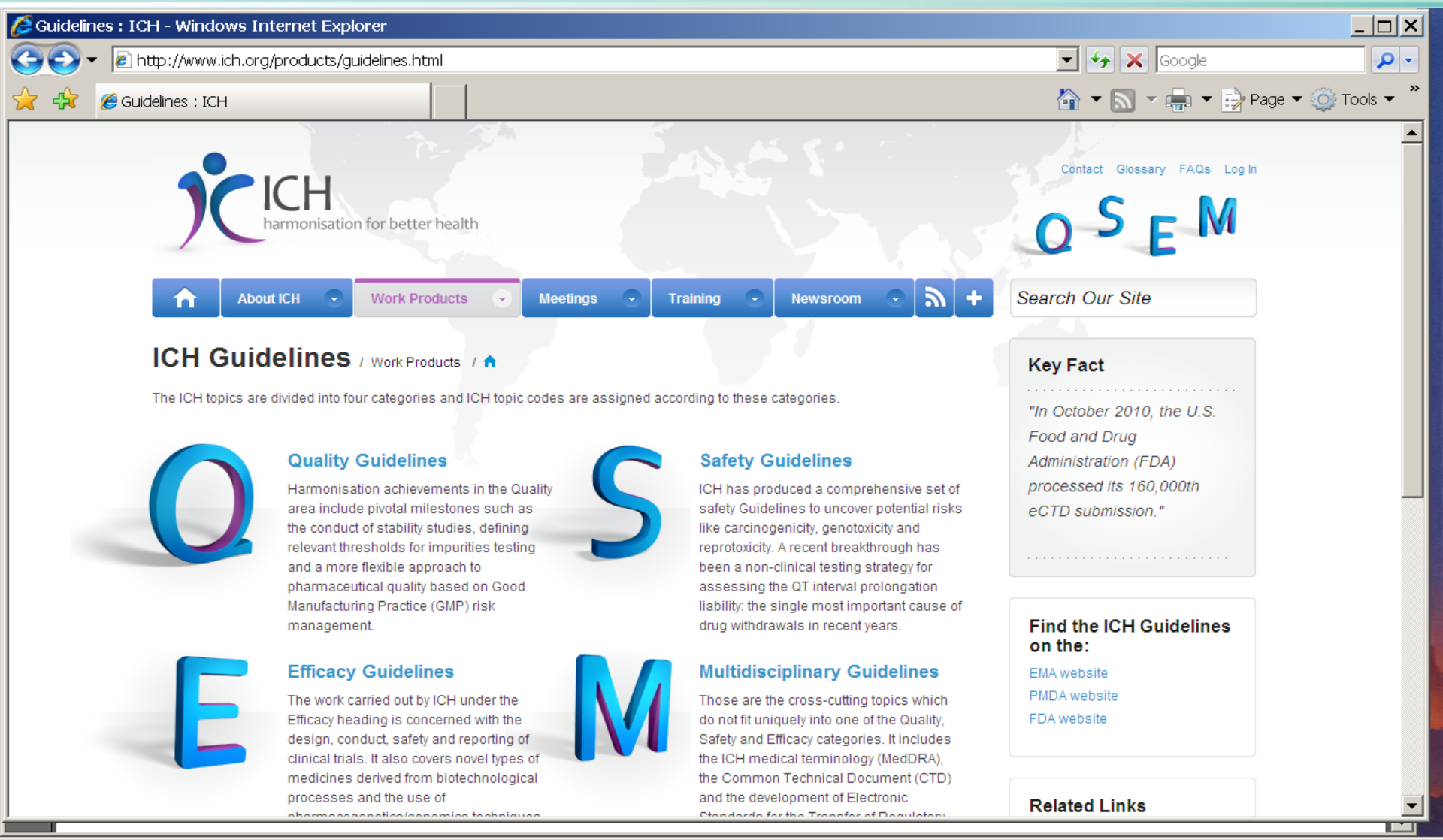
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Ann Meeker O'Connell at 301-796-3150, (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800, or (CDRH) Chrissy Cochran at 301-796-5490.

2011

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
August 2011
Procedural

http://www.ich.org



FTM-EC-SOPs

Quality System Documentation

Document No.: FTM ECS-001-04 | Effective Date: 22 December 2011 | Page **1** of **8**

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

Document No.: FTM ECS-002-03 | Effective Date: 22 April 2010 | Page **1** of **8**

1.0 PURPOSE

To describe the
constituted Ethi
Mahidol Univer

2.0 SCOPE

This SOP will a
of any supportin

3.0 POLICY

The EC assists r
conducting initi
members/studer
facilities. The E
and ICH GCP G

Review of the Informed Consent

Document No.: FTM ECS-006-03 | Effective Date: 22 April 2010 | Page **1** of **7**

1.0 PURPOSE

To describe the processes for the review of informed consent documents submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This SOP will apply to all informed consent documents that accompany research proposal/protocol submitted to FTM EC for review.

3.0 POLICY

3.1 In obtaining and documenting informed consent, the Investigator should comply with the applicable regulatory requirement(s), and should adhere to the ethical principles that have their origin in the Declaration of Helsinki.

3.2 Prior to the beginning of the trial, the Investigator should have the FTM EC's written approval on the written informed consent form and any other written

Role & Responsibility of Investigator

Investigator: Qualifications and Agreements

- qualified by education, training, and experience to assume responsibility for the proper conduct of the trial
- provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation
- familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure
- aware of Good Clinical Practice & the applicable regulatory requirements
- must permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies)
- maintain a list of appropriately qualified persons to whom the investigator has dele

Can investigator plan a study on children without pediatrician?

Investigator: Adequate Resources

- able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period
- have sufficient time to properly conduct and complete the trial within the agreed trial period
- have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely
- ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions

How many studies can one researcher commit to?

Investigator: Medical Care of Trial Subjects

- ensure a qualified physician, either yourself or a sub-investigator, will be responsible for all trial-related medical decisions
- ensure that adequate medical care is provided to a subject for any adverse events (including clinically significant laboratory values) related to the trial, both during and following a subject's participation in a trial
- inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed
- inform a subject when medical care is needed for intercurrent illness(es)
- oblige to give his/her reason(s) for withdrawing prematurely from a trial

If any unanticipated event happens to a study participant, what will be done?

Investigator: Communication with the IRB

- have written and dated approval from the IRB for the research application, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects
- provide / update (if any) the IRB with a current copy of the Investigator's Brochure.
- provide the IRB with all documents subject to review according to the IRB's requirements

If the researchers want to revise a question in their questionnaire after the study has launched, can they do it?

Investigator:
Compliance with the IRB-Approved Research Application

- conduct the research in compliance with the research application that was given approval by the IRB
- not implement any deviation from the IRB-approved research application without prior review and documented approval from the IRB of a modification
- As the investigator, if you deviate from the IRB-approved research application to eliminate an immediate hazard(s) to research subjects without prospective IRB approval, submit a modification and explain the deviation to the IRB

How much that we can tolerate protocol deviation?

Investigator: Investigational Product(s)

- take responsibility for investigational product(s) accountability at the research site(s)
- (you or a designee) maintain records of the product's delivery to the research site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s)
- ensure that the investigational product(s) will be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s)
- used only in accordance with the IRB-approved research application
- explain the correct use of the investigational product(s) to each subject
- periodically check that each subject is following the instructions properly

Investigator: Randomization Procedures and Unblinding

- follow the trial's randomization procedures, if any
- ensure that the code is broken only in accordance with the IRB-approved research application
- (If the research is blinded), promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s)

Is there blinding and unblinding procedures explained in the protocol?

Investigator: Informed Consent of Trial Subjects

- comply with the applicable regulatory requirement(s) and adhere to GCP and to the ethical principles
- must have the IRB's written approval of the written or revised informed consent form and any other written information
- ensure that neither you nor the research staff will coerce or unduly influence a subject to participate or to continue to participate
- fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the research including the written information and the approval by the IRB

Do the researchers use the PIS/ICF of the version stamped by IRB?

Investigator: Records and Reports

- ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs & in all required reports
- ensure that data reported on the CRF are consistent with the source documents If there are any discrepancies, they should be explained.
- ensure that any change or correction to a CRF are dated, initialed, and explained (if necessary) and will not obscure the original entry (i.e., an audit trail should be maintained). This applies to both written and electronic corrections.
- ensure that the financial aspects of the study are documented in an agreement between yourself and the sponsor
- make available for direct access research documents and all requested research-related records upon request of the monitor, auditor, IRB, or regulatory authority

Can IRB ask to look at certain CRF records?

Investigator: Progress Reports

- submit written summaries of the research status to the IRB annually, or more frequently if requested by the IRB
- provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the research, and/or increasing risks to subjects

How often IRB requires to see a progress report?

Investigator: Safety Reporting

- immediately report all SAEs to sponsor, except for SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting
- the immediate and follow-up reports should identify subjects by unique code numbers rather than by names, personal identification numbers, and/or addresses.
- comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the IRB and regulatory authority(ies)
- report adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified in the protocol
- supply the sponsor and the IRB with any additional requested information for reported deaths (e.g., autopsy reports and terminal medical reports)

Investigator:
Premature Termination or Suspension of Trial

- if the trial is prematurely terminated or suspended for any reason, promptly inform the trial subjects, assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), inform the regulatory authority(ies)
- if you terminate or suspend research without prior agreement of the sponsor, provide the sponsor and the IRB with a detailed written explanation of the termination or suspension
- If the sponsor terminates or suspends a trial, the investigator promptly inform the IRB and provide a detailed written explanation of the termination or suspension
- If the IRB terminates or suspends its approval of your research, you notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension

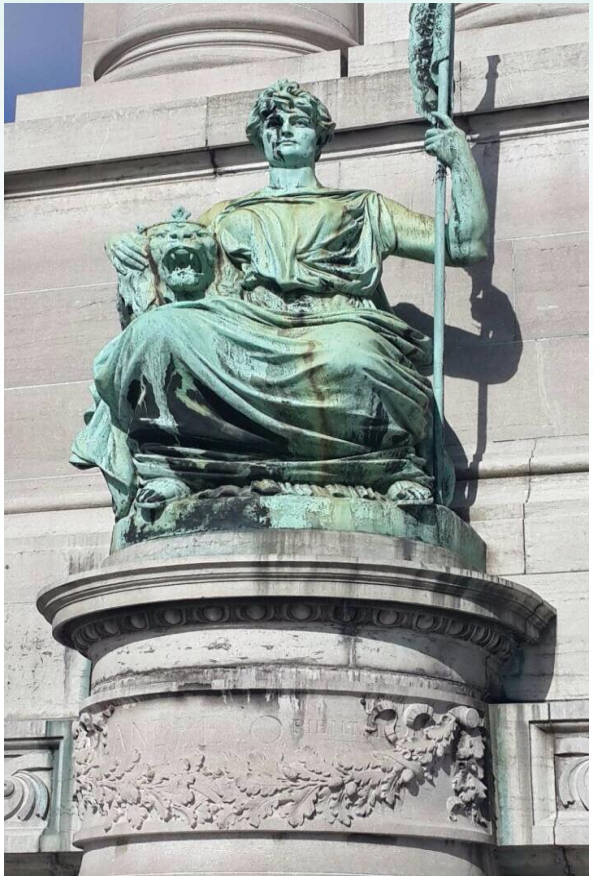
Can IRB terminate the study?

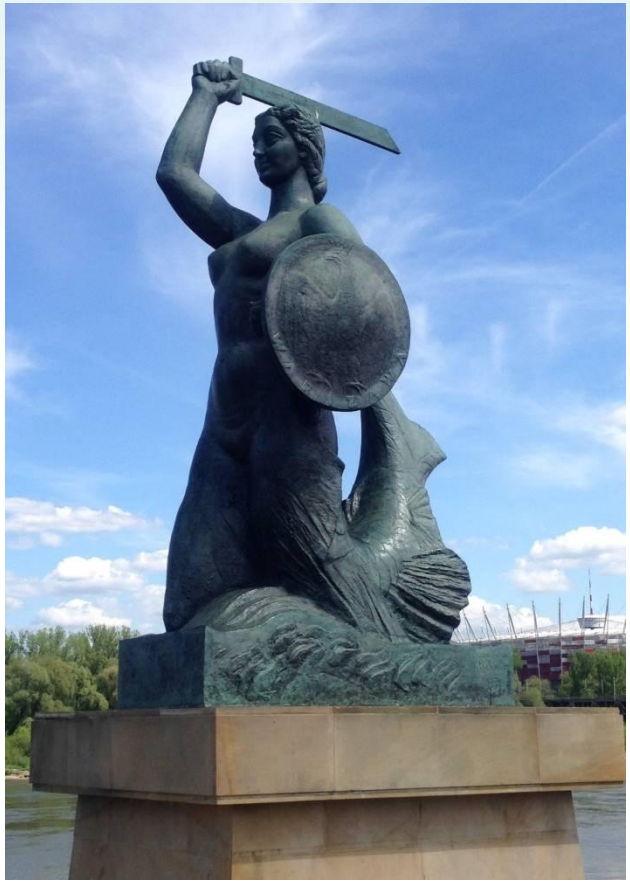
Investigator: Final Report(s) by Investigator

- inform the IRB and provide a summary of the research results, and provide any reports required by the regulatory authority(ies)

Do the researcher submit the final study report?

Role & Responsibility of IEC - IRB





IEC - IRB: Composition, Functions, and Operations

- consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial
- recommended compositions:
  - At least five members.
  - At least one member whose primary area of interest is in a nonscientific area.
  - At least one member who is independent of the institution
- Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.
- maintain a list of IRB/IEC members and their qualifications should be maintained.

IEC - IRB: Composition, Functions, and Operations

- perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).
- make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present
- may invite nonmembers with expertise in special areas for assistance.

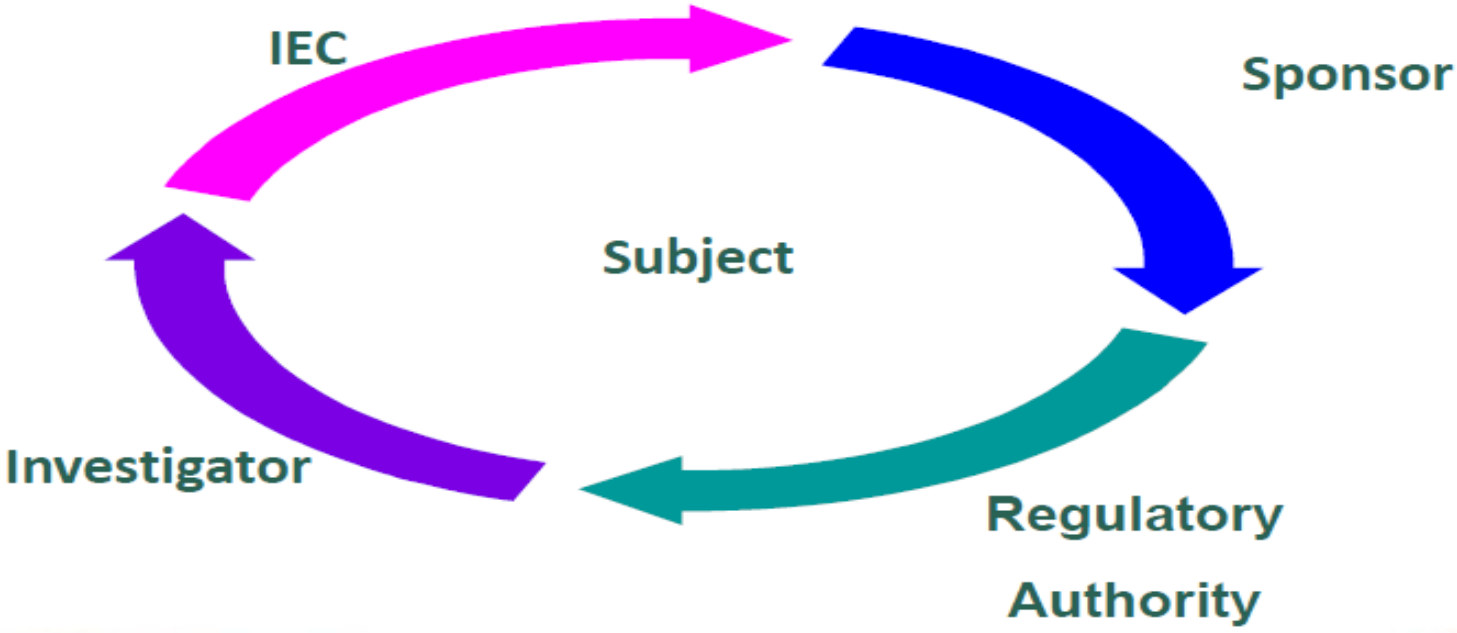
At audit –
IRB is functioning according to its SOPs?

IEC - IRB: Roles & Responsibilities

- safeguard the rights, safety, and well-being of all trial subjects; special attention to vulnerable subjects.
- obtain and review the following documents:
  - trial protocol(s)/amendment(s),
  - written informed consent form(s) and consent form updates
  - subject recruitment procedures (e.g., advertisements), written information)
  - Investigator's Brochure (IB)
  - information about payments and compensation
  - curriculum vitae and/or other documentation evidencing qualifications
  - other documents required to fulfil its responsibilities.

IEC - IRB: Roles & Responsibilities

Protection of human subjects is the responsibility of:



Courtesy: Dr. Niwat Montreewasuwat (modified)

IEC - IRB: Roles & Responsibilities

Roles & Responsibilities of IRB/IEC

Documents for EC Review

Courtesy: Dr. Niwat Montreewasuwat (modified)

IEC - IRB: Roles & Responsibilities

Documents for EC Review

Documents Requiring IEC Opinion:

- Protocol and amendments
- Informed consent forms
- Additional information given to subjects
- Recruitment advertisements
- Payments to subjects

Documents for EC Review

Documents requiring IEC review:

- Investigator Brochure (IB) and addenda
- Serious Adverse Events (SAE) reports
- Administrative letters
- Final investigator study report
- Annual study status updates from investigators

IEC - IRB: Responsibilities

- consider the qualifications of the investigator
- conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.
- request more information than the above outlined when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety, and/or well-being of the subjects.

IRB approval for one year!

IEC - IRB: Responsibilities

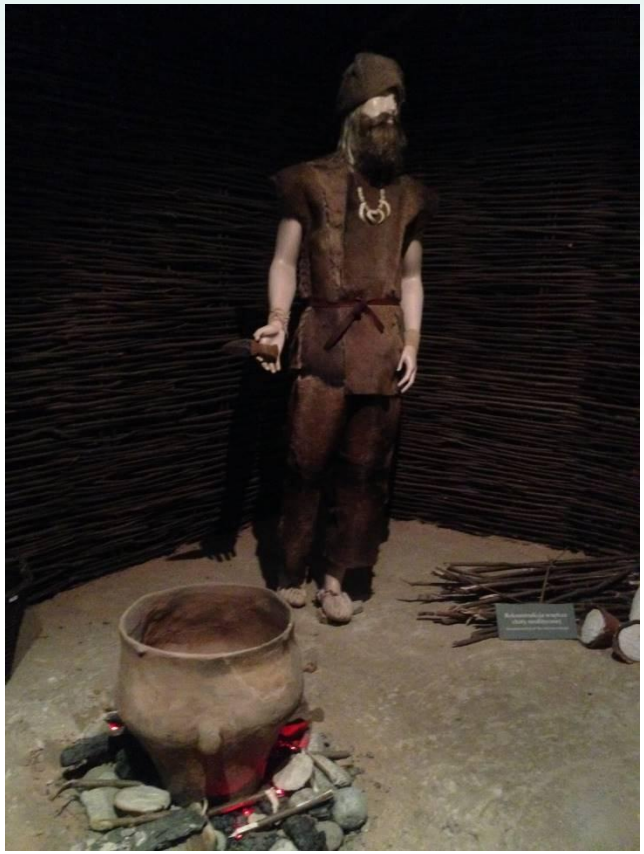
- review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence; payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.
- ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent

Can the investigator not provide any compensation to the study participants?

IEC - IRB: Procedures

- Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:
  (a) Its trial-related decisions/opinions.
  (b) The reasons for its decisions/opinions.
  (c) Procedures for appeal of its decisions/opinions.
- retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial
- make them available upon request from the regulatory authority(ies).
- may be asked by investigators, sponsors, or regulatory authorities to provide copies of its written procedures and membership lists.

Some issues in use of specimen & data



Study using - Archived Specimen & Medical Records

Roles & Responsibilities of IRB/IEC

ข้อบังคับแพทยสภาว่าด้วยการรักษาจริยธรรมแห่งวิชาชีพเวชกรรม (ฉบับที่ ๕) พ.ศ. ๒๕๔๔

หมวด ๖ การศึกษาวิจัยและการทดลองในมนุษย์ (ข้อ ๑)

- "การศึกษาวิจัยและการทดลองในมนุษย์" หมายความว่าการศึกษาวิจัยและการทดลองเภสัชภัณฑ์ เครื่องมือแพทย์ การศึกษาธรรมชาติของโรค การวินิจฉัย การรักษา การส่งเสริมสุขภาพและการป้องกันโรคที่กระทำต่อมนุษย์ รวมทั้งการศึกษาวิจัยจากเวชระเบียนและสิ่งส่งตรวจต่างๆจากร่างกายของมนุษย์ด้วย

ประกาศในราชกิจจานุเบกษา ฉบับประกาศทั่วไป เล่ม ๑๑๙ ตอนที่ ๑๒ง วันที่ ๙ กุมภาพันธ์ ๒๕๔๕ บังคับใช้เมื่อพ้นกำหนด ๑๙๐ วันนับแต่วันถัดจากวันประกาศในราชกิจจานุเบกษาเป็นต้นไป คือ ๑๙ สิงหาคม ๒๕๔๕

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Roles & Responsibilities of IRB/IEC

ข้อบังคับแพทยสภาว่าด้วยการรักษาจริยธรรมแห่งวิชาชีพเวชกรรม (ฉบับที่ ๒) พ.ศ. ๒๕๔๙ *หมวด ๑ บทนิยาม*

- "การศึกษาวิจัยและการทดลองในมนุษย์" หมายความว่าการศึกษาวิจัยและการทดลองเภสัชภัณฑ์ เครื่องมือแพทย์ การศึกษาธรรมชาติของโรค การวินิจฉัย การรักษา การส่งเสริมสุขภาพและการป้องกันโรค ที่กระทำต่อมนุษย์ รวมทั้งการศึกษาวิจัยจากเวชระเบียนและสิ่งส่งตรวจต่างๆจากร่างกายของมนุษย์ด้วย

ประกาศในราชกิจจานุเบกษา เล่ม ๑๒๓ ตอนพิเศษ ๑๑๕ง วันที่ ๑ พฤศจิกายน ๒๕๔๙

Bumrungrad International HOSPITAL

Study using - Archived Specimen & Medical Records

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Roles & Responsibilities of IRB/IEC

พระราชบัญญัติสุขภาพแห่งชาติ ๒๕๕๐

- มาตรา ๙ ในกรณีที่ผู้ประกอบวิชาชีพด้านสาธารณสุขประสงค์จะใช้ผู้รับบริการเป็นส่วนหนึ่งของการทดลองในงานวิจัย ผู้ประกอบวิชาชีพด้านสาธารณสุขต้องแจ้งให้ผู้รับบริการทราบล่วงหน้าและต้องได้รับความยินยอมเป็นหนังสือจากผู้รับบริการก่อนจึงจะดำเนินการได้ ความยินยอมดังกล่าวผู้รับบริการจะเพิกถอนเสียเมื่อใดก็ได้
  - มาตรา ๗ ข้อมูลด้านสุขภาพของบุคคล เป็นความลับส่วนบุคคล ผู้ใดจะนำไปเปิดเผยในประการที่น่าจะทำให้บุคคลนั้นเสียหายไม่ได้ เว้นแต่การเปิดเผยนั้นเป็นไปตามความประสงค์ของบุคคลนั้นโดยตรง หรือมีกฎหมายเฉพาะบัญญัติให้ต้องเปิดเผย แต่ไม่ว่ากรณีใด ๆ ผู้ใดจะอาศัยอำนาจหรือสิทธิตามกฎหมายว่าด้วยข้อมูลข่าวสารของราชการหรือกฎหมายอื่นเพื่อขอเอกสารเกี่ยวกับข้อมูลด้านสุขภาพของบุคคลที่ไม่ใช่ของตนไม่ได้
  - มาตรา ๘ ในการบริการสาธารณสุข บุคลากรด้านสาธารณสุขต้องแจ้งข้อมูลด้านสุขภาพที่เกี่ยวข้องกับการให้บริการให้ผู้รับบริการทราบอย่างเพียงพอที่ผู้รับบริการจะใช้ประกอบการตัดสินใจในการรับหรือไม่รับบริการใด และในกรณีที่ผู้รับบริการปฏิเสธไม่รับบริการใด จะให้บริการนั้นมิได้
  - ความในวรรคหนึ่งมิให้ใช้บังคับกับกรณีดังต่อไปนี้
    - (๑) ผู้รับบริการอยู่ในภาวะที่เสี่ยงอันตรายถึงชีวิตและมีความจำเป็นต้องให้ความช่วยเหลือเป็นการรีบด่วน
    - (๒) ผู้รับบริการไม่อยู่ในฐานะที่จะรับทราบข้อมูลได้ และไม่อาจแจ้งให้บุคคลซึ่งเป็นทายาทโดยธรรมตามประมวลกฎหมายแพ่งและพาณิชย์ ผู้ปกครอง ผู้ปกครองดูแล ผู้พิทักษ์ หรือผู้อนุบาลของผู้รับบริการแล้วแต่กรณี รับทราบข้อมูลแทนในขณะนั้นได้

มาตรา ๔๙ ผู้ใดฝ่าฝืนมาตรา ๗ หรือมาตรา ๙ ต้องระวางโทษจำคุกไม่เกินหกเดือน หรือปรับไม่เกินหนึ่งหมื่นบาท หรือทั้งจำทั้งปรับ ความผิดตามมาตรานี้เป็นความผิดอันยอมความได้

Roles & Responsibilities of IRB/IEC

การทดลองในมนุษย์ตามกฎหมายอาญาของไทย

- การทดลองในมนุษย์ในกรณีที่มีการกระทำครบองค์ประกอบความผิดฐานทำร้ายร่างกาย ผู้ทำการทดลองจะต้องรับผิดตามประมวลกฎหมายอาญา ซึ่งจะเป็นไปตามมาตราใดบ้างย่อมขึ้นอยู่กับผลของการทดลอง... อย่างไรก็ตาม แม้การทดลองจะเป็นการกระทำที่ครบองค์ประกอบความผิดดังกล่าว แต่ก็มีเหตุที่ทำให้ผู้กระทำมีอำนาจกระทำได้ (เหตุลบล้างความผิดกรณีการทดลองในมนุษย์) ด้วยเหตุผลสองประการ

  ก. หลักความยินยอมของผู้เสียหาย

  ๑. ความยินยอมนั้นต้องบริสุทธิ์

  ๒. ความยินยอมนั้นจะต้องมีอยู่จนถึงขณะทำการอันกฎหมายบัญญัติว่าเป็นความผิด

  ๓. ความยินยอมนั้นต้องไม่ขัดต่อสำนึกในศีลธรรมอันดี

  ข. หลักการชั่งน้ำหนักระหว่างความคุณธรรมทางกฎหมาย

จเนก ยมจินดา ใน แสวง บุญเฉลิมวิภาส และ จเนก ยมจินดา *กฎหมายการแพทย์* กรุงเทพฯ: วิญญูชน ๒๕๔๖ พิมพ์ครั้งที่ ๒ หน้า ๓๑๔-๓๒๕.

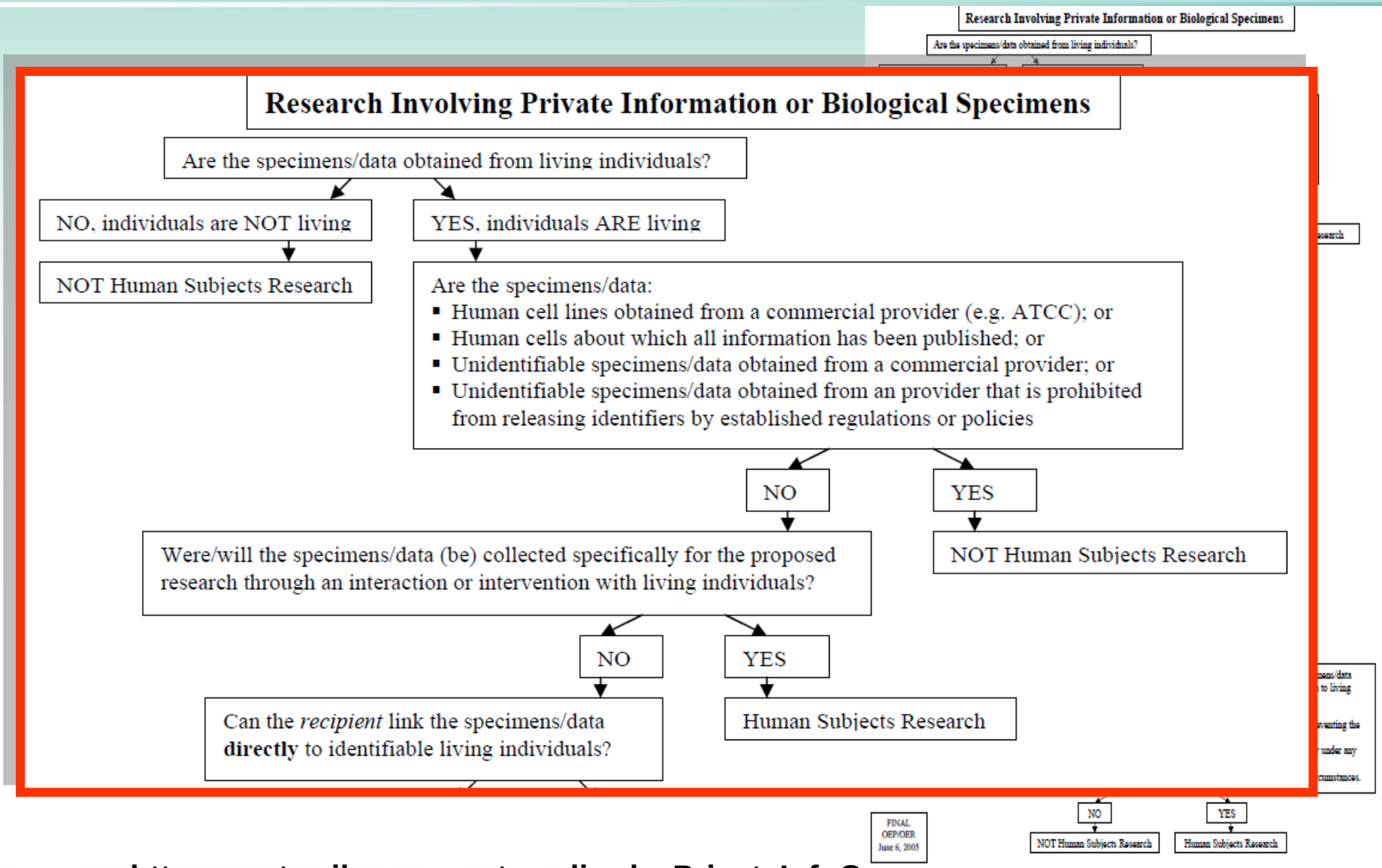
Roles & Responsibilities of IRB/IEC

คำประกาศสิทธิของผู้ป่วย
แพทยสภา สภาการพยาบาล สภาเภสัชกรรม ทันตแพทยสภา กระทรวงสาธารณสุข
ร่วมกันประกาศสิทธิผู้ป่วย ๑๖ เมษายน ๒๕๔๑

- ผู้ป่วยทุกคนมีสิทธิพื้นฐานที่จะได้รับบริการด้านสุขภาพตามที่บัญญัติไว้ในรัฐธรรมนูญ
- ผู้ป่วยมีสิทธิที่จะได้รับบริการจากผู้ประกอบวิชาชีพด้านสุขภาพ โดยไม่มีการเลือกปฏิบัติ เนื่องจากความแตกต่างด้านฐานะ เชื้อชาติ สัญชาติ ศาสนา สังคม ลัทธิการเมือง เพศ อายุ และลักษณะของความเจ็บป่วย
- ผู้ป่วยที่จะขอรับบริการด้านสุขภาพมีสิทธิที่จะได้รับทราบข้อมูลอย่างเพียงพอและเข้าใจชัดเจนจากผู้ประกอบวิชาชีพด้านสุขภาพ เพื่อให้ผู้ป่วยสามารถเลือกตัดสินใจในการยินยอมหรือไม่ยินยอมให้ผู้ประกอบวิชาชีพด้านสุขภาพปฏิบัติต่อตน เว้นแต่เป็นการช่วยเหลือรีบด่วนหรือจำเป็น
- ผู้ป่วยที่อยู่ในภาวะเสี่ยงอันตรายต่อชีวิต มีสิทธิที่จะได้รับการช่วยเหลือรีบด่วนจากผู้ประกอบวิชาชีพด้านสุขภาพ โดยทันที ตามความจำเป็นแก่กรณี โดยไม่คำนึงว่าผู้ป่วยจะร้องขอความช่วยเหลือหรือไม่
- ผู้ป่วยมีสิทธิที่จะได้รับทราบ ชื่อ สกุล และประเภทของผู้ประกอบวิชาชีพด้านสุขภาพที่เป็นผู้ให้บริการต่อตน
- ผู้ป่วยมีสิทธิที่จะขอความเห็นจากผู้ประกอบวิชาชีพด้านสุขภาพอื่น ที่มิได้เป็นผู้ให้บริการแห่งตน และมีสิทธิในการขอเปลี่ยนผู้ให้บริการ และสถานบริการได้
- ผู้ป่วยมีสิทธิที่จะได้รับการปกป้องข้อมูลเกี่ยวกับตนเอง จากผู้ประกอบวิชาชีพด้านสุขภาพโดยเคร่งครัด เว้นแต่จะได้รับความยินยอมจากผู้ป่วย หรือการปฏิบัติหน้าที่ตามกฎหมาย
- **ผู้ป่วยมีสิทธิที่จะได้รับทราบข้อมูลอย่างครบถ้วนในการตัดสินใจในการเข้าร่วม หรือถอนตัวจากการเป็นผู้ถูกทดลองในการทำวิจัยของผู้ประกอบการวิชาชีพด้านสุขภาพ**
- ผู้ป่วยมีสิทธิที่จะได้รับทราบข้อมูลเกี่ยวกับการรักษาพยาบาลเฉพาะของตนที่ปรากฏในเวชระเบียน เมื่อร้องขอ ทั้งนี้ข้อมูลดังกล่าวต้องไม่เป็นการละเมิดสิทธิส่วนตัวของบุคคลอื่น
- บิดา มารดา หรือผู้แทนโดยชอบธรรมอาจใช้สิทธิแทนผู้ป่วยที่เป็นเด็กอายุไม่เกินสิบแปดปีบริบูรณ์ ผู้บกพร่องทางกายหรือจิต ซึ่งไม่สามารถใช้สิทธิด้วยตนเองได้

Human Subjects Research

ORS
FTM-EC



http://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf

Types of Specimen to be used

Table 1 Outline of the major characteristics of the five categories of sample labeling

Category	*Link between subject identity and genetic data*	*Records identifiable for clinical monitoring*	*Actions possible if consent is withdrawn*	*Return of individual results to subject*	*Scope of subject privacy*
Identified	Yes, directly	Yes	Sample can be destroyed Data can be deleted[a]	Possible	Similar to general healthcare confidentiality
Coded	Indirectly, via code numbers	Yes, via protocol-specified procedures	Sample can be destroyed Data can be deleted[a]	Possible	Standard for clinical research Conforms to ICH guidelines
De-Identified	Very indirectly via two levels of code numbers	Yes, via protocol-specified procedures	Sample can be destroyed and data can be deleted[a] via protocol-specified procedures	Possible	Offers added privacy over single coding, breached only via specified procedures
Anonymized	No. Key between first and second codes is deleted	No	Sample and data are not identifiable and cannot be destroyed once key is deleted	Not possible	Genetic data not linked to individuals, offering additional security
Anonymous	No	No	None	Not possible	Maximum

[a]Data can be deleted up to the time it is reported, but not thereafter.

Terminology for sample collection in clinical genetic studies

The Pharmacogenetics Working Group*

Use of store specimen

FAQ #4

It is increasingly common to collect and store specimens for future unspecified research. How broad can this consent be without requiring investigators to obtain additional consent for specific uses? Alternatively, how specific must this consent be to allow for future use of biospecimens?

Response. There is a tension between the desire to be as specific as possible when informing subjects of what will be done, and the reality that specifics are, by definition, not known at the time of consent.

Many institutions and IRBs have found it prudent to be general enough in the consent form to give subjects a reasonable idea of the types of research that might be conducted in the future and the associated risks, but without placing unreasonable restrictions on what the research might be. Thus, subjects can be informed that future studies may involve genetic research, drug development, or searching for links between genes and environmental factors like diet or lifestyle, or between genes and diseases. While examples might be given of specific diseases (e.g., cancer, diabetes, heart disease), being overly-specific or restrictive in this regard may result in problems later, when investigators propose other uses. IRBs and investigators should consider the downstream implications before promising subjects that "your specimens will only be used for research on XYZ."

http://www.hhs.gov/ohrp/sachrp/20110124attachmentatosecletter.html

Specimen Transfer

FAQ #16

A clinical trial is funded by an industry sponsor or other entity and the contract provides for specimens to be transferred to the sponsor or other entity.

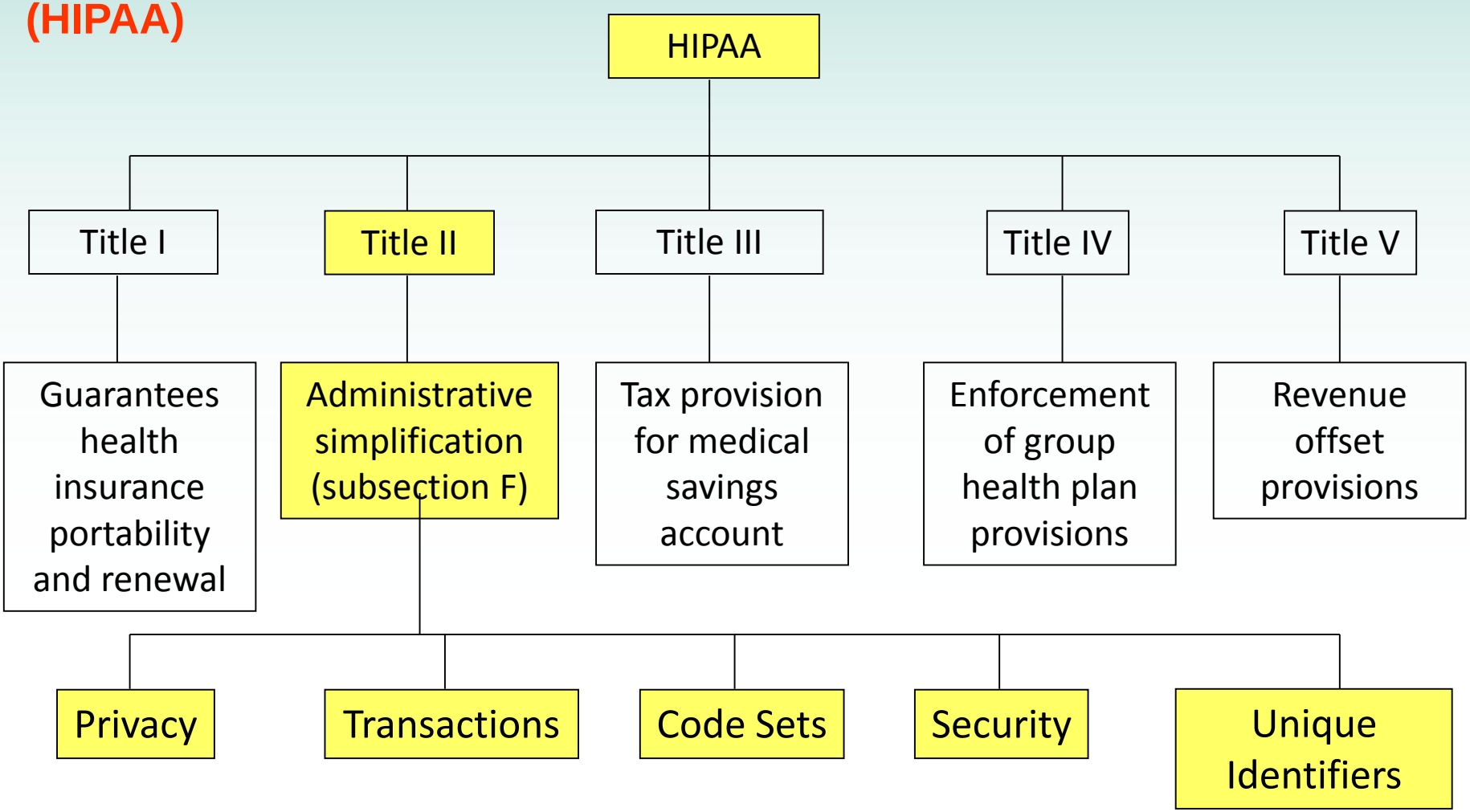
What factors should be considered in such an arrangement?

Response. The consent form should describe the plan to transfer specimens to the company or sponsor. Material Transfer Agreements (MTAs) or other similar legally binding agreements should be in place that describes the rights and obligations of the providing researcher and institution and the industry sponsor. These should include stipulations that the use of the specimens will be compatible with the terms of the consent form and the approved protocol.

http://www.hhs.gov/ohrp/sachrp/20110124attachmentatosecletter.html

Use of protected health information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)



Source: John Butterworth, Ethics and Clinical Research

Protected Health Information (PHI)

What is Covered in the Privacy Rule?

- **Health information + Identifier = PHI**
- Transmitted or maintained in any form (paper, electronic, web-based, etc.)
- Decedents' information included
- Does not include de-identified health information

Source: John Butterworth, Ethics and Clinical Research

The Privacy Rule defines 18 identifiers

- Name
- Geographic information (including city, state and zip)
- Elements of dates (including admission/discharge dates; service dates; birth date, date of death)
- Telephone numbers
- FAX numbers
- E-mail addresses
- Social Security number
- Medical Record number, prescription number, etc.
- Health plan beneficiary number
- Account Numbers
- Certification numbers
- VIN and Serial numbers, license plate numbers
- Device identifiers and serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers (finger prints, voice prints, retinal scans, etc.)
- Full face or comparable photo images
- Unique identifying numbers

Source: John Butterworth, Ethics and Clinical Research

Use of PHI

Research Use and Disclosure of PHI Without Authorization: Preparatory to Research

- Requires notification of the entity holding the PHI
- Researcher must provide representation that:
  - PHI is to be used solely to prepare a protocol or a similar purpose
  - PHI will not be removed from the covered entity
  - PHI is necessary for research
- May be used to develop hypothesis, protocol or characteristics of research cohort
- May not be summarized, used or presented as a research study without prior IRB approval
- May allow access to PHI to identify subjects for recruitment

Source: John Butterworth, Ethics and Clinical Research

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Source: John Butterworth, Ethics and Clinical Research

International Medical Informatics Association

The IMIA Code of Ethics for Health Information Professionals

A. Fundamental Ethical Principles

All social interactio
setti
of th

You get permission – can you see the medical records?!

Use medical records from Hospital? Cannot ask for informed consent!

1. *Prin*

Conduct HIV preventive vaccine in Thailand/Africa a lot – Is it fair?

2. *Principle of Equality and Justice*
   All persons are equal as persons and have a right to be treated accordingly.

3. *Principle of Beneficence*
   All persons have a duty to advance the good of others where the nature of

As you look at EMR of your friend – a husband has HIV, will you tell his wife?

4. *Principle of Non-Malfeasance*
   All persons have a duty to prevent harm to other persons insofar as it lies within their power to do so without undue harm to themselves.

5.*Pri*

The subsequent analysis suggests that some data in the system are wrong and you cannot recollect the data – what to do?

6. *Principle of Integrity*
   Whoever has an obligation, has a duty to fulfil that obligation to the best of her or his ability.

Collect data from subject without bias

International Medical Informatics Association

The IMIA Code of Ethics for Health Information Professionals

We have individual data in malaria national database (Thai & migrant cases). A research team from a western country ask for data to use in their study.
- Should we give the data out? Why?
- If yes, what data can be given to the research team?

1. *Principle of Information-Privacy and Disposition*

   All persons have a fundamental right to privacy, and hence to control over the collection, storage, access, use, communication, manipulation and disposition of data about themselves.

2. *Principle of Openness*

   The collection, storage, access, use, communication, manipulation and disposition of personal data must be disclosed in an appropriate and timely fashion to the subject of those data.

3. *Principle of Security*

   Data that have been legitimately collected about a person should be protected by all reasonable and appropriate measures against loss, degradation, unauthorized destruction, access, use, manipulation, modification or communication.

International Medical Informatics Association

The IMIA

Who own the personal data record – patient or hospital?
Can the patient has right to see his/her record?

B. General Pri

4. *Principle of Access*

The subject of an electronic record has the right of access to that record and the right to correct the record with respect to its accurateness, completeness and relevance.

5. *Principle of Legitimate Infringement*

The fundamental right of control over the collection, storage, access, use, manipulation, communication and disposition of personal data is conditioned only by the legitimate, appropriate and relevant data-needs of a free, responsible and democratic society, and by the equal and competing rights of other persons.

Collect only data needed, not irrelevant data !

6. *Principle of the Least Intrusive Alternative*

Any infringement of the privacy rights of the individual person, and of the individual's right to control over person-relative data as mandated under *Principle 1*, may only occur in the least intrusive fashion and with a minimum of interference with the rights of the affected

7. *Principle of Accountability*

Any infringement of the privacy rights of the
to control over person-relative data, must be
good time and in an appropriate fashion.

Hospital takes picture of patient when he/she register onto the hospital
– Is it OK?

Discussion ….