Regulation on Human Subject Research in Taiwan

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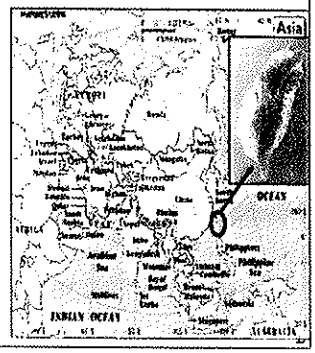
1

Discover Taiwan

- Area: 36,188km² (1/10 of Malaysia, 1/14 of Thailand)
- Population: 23 million
- GDP per capita: US$16,792
- Literacy: 95.8%
- Health expenditure: ~6% GDP

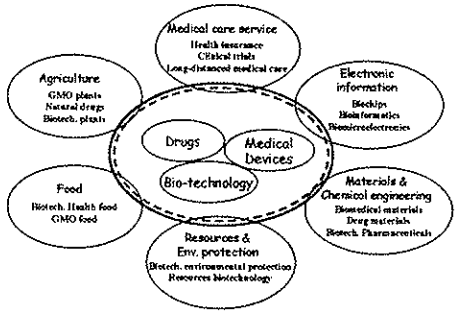


Health care system in Taiwan

- Primary Care Clinics no.:19,135
- Acute care Hospital no.: 547
  - more than 500 beds: 105 (19.0%)
  - more than 1000 beds: 35 (6.4%)
  - more than 2500 beds: 5 (3.7%)
- Most of hospitals(85%) are private or juridical
- National health insurance coverage: >99% (since 1994)

3

Development of Health Biotechnological Industries in Taiwan



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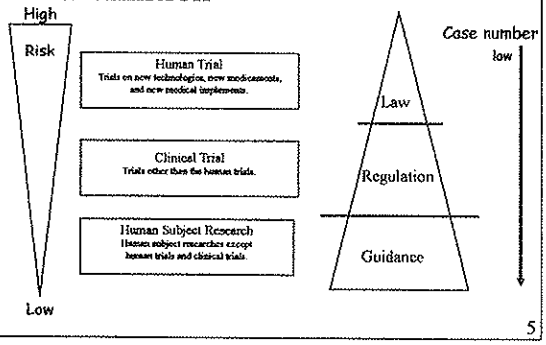
Definition



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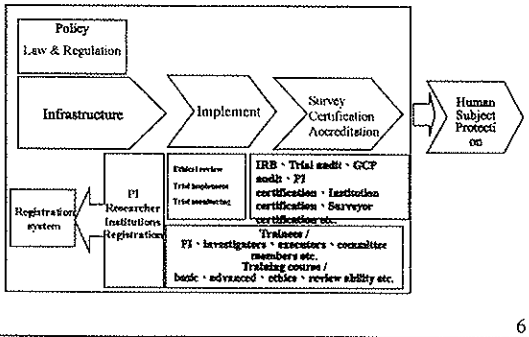
Spectrum of Human Subjects Protection



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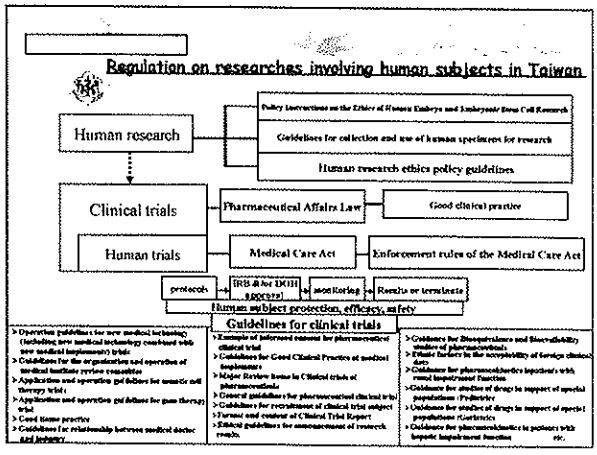
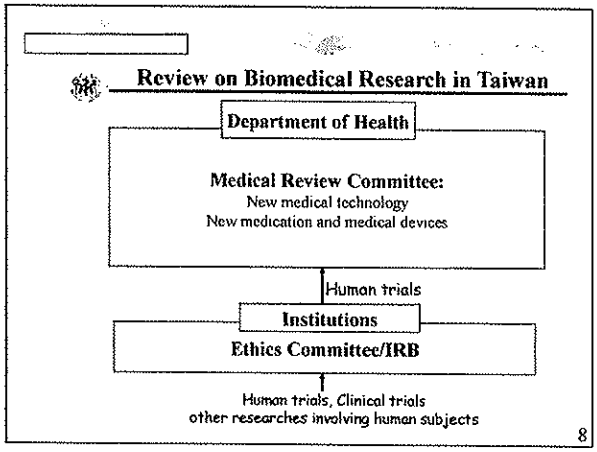
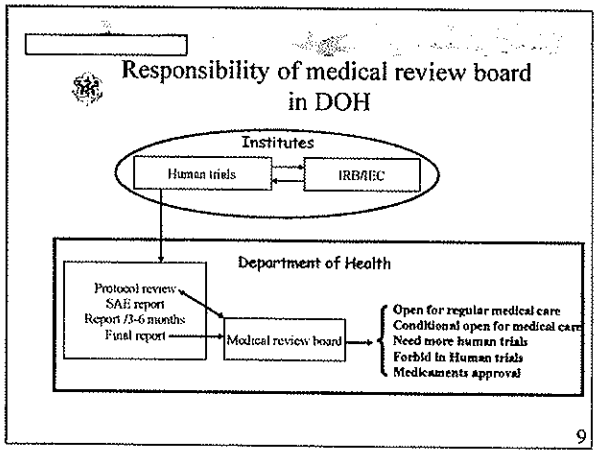
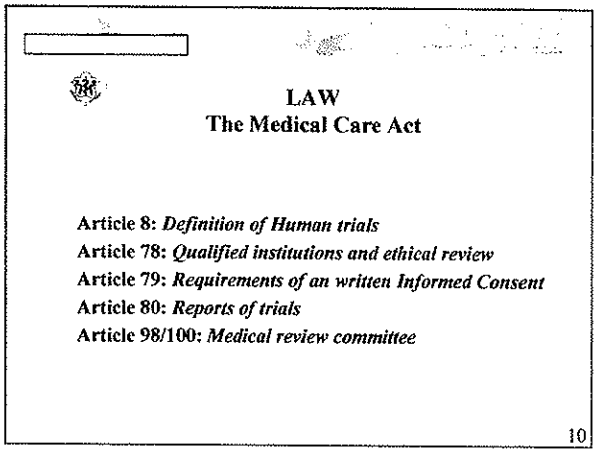
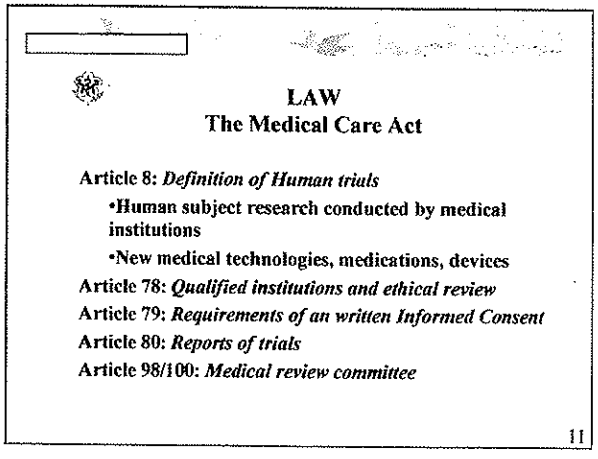
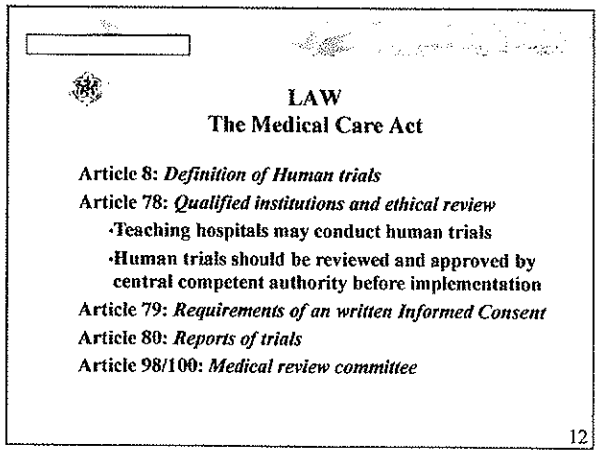

Regulation on researches involving human subjects in Taiwan
Human research
Clinical trials
Human trials
Pharmaceutical Affairs Law
Good clinical practice
Medical Care Act
Enforcement rules of the Medical Care Act
protocols
Human subject protection, efficacy, safety
Guidelines for clinical trials


Review on Biomedical Research in Taiwan
Department of Health
Medical Review Committee:
New medical technology
New medication and medical devices
Human trials
Institutions
Ethics Committee/IRB
Human trials, Clinical trials
other researches involving human subjects
8


Responsibility of medical review board
in DOH
Institutes
Human trials
IRB/IEC
Department of Health
Protocol review
SAE report
Report /3-6 months
Final report
Medical review board
Open for regular medical care
Conditional open for medical care
Need more human trials
Forbid in Human trials
Medicaments approval
9


LAW
The Medical Care Act
Article 8: Definition of Human trials
Article 78: Qualified institutions and ethical review
Article 79: Requirements of an written Informed Consent
Article 80: Reports of trials
Article 98/100: Medical review committee
10


LAW
The Medical Care Act
Article 8: Definition of Human trials
•Human subject research conducted by medical institutions
•New medical technologies, medications, devices
Article 78: Qualified institutions and ethical review
Article 79: Requirements of an written Informed Consent
Article 80: Reports of trials
Article 98/100: Medical review committee
11


LAW
The Medical Care Act
Article 8: Definition of Human trials
Article 78: Qualified institutions and ethical review
·Teaching hospitals may conduct human trials
·Human trials should be reviewed and approved by central competent authority before implementation
Article 79: Requirements of an written Informed Consent
Article 80: Reports of trials
Article 98/100: Medical review committee
12

LAW
The Medical Care Act

Article 8: *Definition of Human trials*
Article 78: *Qualified institutions and ethical review*
Article 79: *Requirements of an Informed Consent*
- Purpose and methods
- Possible side effects / risks
- Expected results
- Alternatives
- Retraction

Article 80: *Reports of trials*
Article 98/100: *Medical review committee*

13

LAW
The Medical Care Act

Article 8: *Definition of Human trials*
Article 78: *Qualified institutions and ethical review*
Article 79: *Requirements of an written Informed Consent*
Article 80: *Reports of trials*
- Should submit reports during and after trials
- Cease trial immediately if safety concerned

Article 98/100: *Medical review committee*

14

LAW
The Medical Care Act

Article 8: *Definition of Human trials*
Article 78: *Qualified institutions and ethical review*
Article 79: *Requirements of an written Informed Consent*
Article 80: *Reports of trials*
Article 98/100: *Medical review committee*
- Members include medical experts, legal experts, scholars, and social personages.
- legal experts and social personages should account for one-third of members at least

15

Human Trials in Taiwan

	2004		2005		2006		2007	
	P	S	P	S	P	S	P	S
Taiwan single site	32	32	24	24	11	11	21	21
Taiwan multiple sites	25	88	10	43	22	74	20	81
Multi-Nation (MN) trials	62	196	86	284	100	337	127	479
% of MN trials, P	52.1%		71.7%		75%		75.6%	
總計	119	316	120	351	133	422	168	581

P: protocol S: site

16

GUIDELINES

For ethical committee:
- Guidelines for the organization and operation of medical institute review committee

For review process:
- Types of trials for expedited review
- Major Review Issues in Clinical trials of pharmaceuticals

For general trials:
- Guidelines for recruitment of clinical trial subject
- Ethical guidelines for announcement of research results
- Guidelines for relationship between medical doctor and industry
- Format and content of Clinical Trial Report

For informed consent:
- Example of Informed consent for pharmaceutical clinical trial
- Guidance for informed consent form of pharmacogenetic research

For specific trials:
- Application and operation guideline for somatic cell therapy trials
- Application and operation guideline for gene therapy trials
- Good tissue practice
- Operation guideline for new medical technology (including new medical technology combined with new medical implements) trials

For specific trials (continued):
- Guidance for Bioequivalence and Bioavailability studies of pharmaceuticals
- General guidelines for pharmaceutical clinical trial
- Guideline for Good Clinical Practice of medical implements
- Ethnic factors in the acceptability of foreign clinical data
- Guidance for pharmacokinetics in patients with renal impairment function
- Guidance for studies of drugs in support of special populations :Pediatrics
- Guidance for studies of drugs in support of special populations :Geriatrics
- Guidance for pharmacokinetics in patients with hepatic impairment function

For human researcher
- Guidelines for Collection and Use of Human Specimens for Research
- Human Research Ethics Policy Guidelines
- Policy instructions on the ethics of human embryo and embryonic stem cell research

17

Human Research Ethics Policy Guidelines
July 17, 2007

- Purpose of Human research
- Definition of Human research
- Informed consent
- Commercial benefit
- Consent research only
- vulnerable population
- Confidential and risk control
- Ethics committee

18

Hospital Accreditation in Taiwan

1978-1987	Teaching hospitals accredited by Ministry of Education (MOE) and Department of Health (DOH)
1986	DOH enacted Medical Care Act which requires statutory regulations of hospital accreditation (Medical Care Act #28, #94, #95)
1988	MOE officially transferred its Teaching Hospital Accreditation to DOH, which begins offering accreditation to hospitals
1990	Accreditation required by National Labor Insurance which prompted 493 hospitals to apply for accreditation
1999	DOH established YJCHA for Hospital accreditation, accreditation for district hospitals began
2000	Accreditation for regional hospitals and psychiatry hospitals began.
2003	Accreditation reforms: standards are revised to emphasize quality of process and outcome in healthcare performance, instead of healthcare organization's structure
2004	Reformed accreditation has been adopted to Medical Centers.
2006	Reformed accreditation has been adopted to all hospitals nationwide
2007-	Fee charging accreditation began

19

Accreditation Standards for Hospital
Chapter 3 Patient Rights & Patient Safety

3.1 Respect for Patient Rights & Establishing Good Physician -Patient Relationships
3.2 Communication for Medical Care & Consent from Patients & Their Families
3.3 Systems to Ensure Patient Safety
3.4 Establishing a Medical Environment that Ensures Patient Safety
3.5 Collecting & Analyzing Information on Patient Safety for Review and Improvement
3.6 Managing Medical Adverse Events
3.7 Infection Control Operations
3.8 Ensuring Patient Medication Safety

20

Accreditation Standards for Teaching Hospital
Chapter 3 Research implementation and result

3.1 Launch good incentive programs for research.
3.2 Implementation and results of researches.
3.3 Human subject research.
  3.3.1 The organization and operation of IEC/IRBs.
  3.3.2 Informed consent procurement and human subject protection.
  3.3.3 Operation of review and monitoring mechanism on human subject research.

21

Institutional Review Boards in Taiwan

- 任務：臨床試驗計畫及人體研究計畫之倫理審查
  Ethical Review of Clinical Trials and other Researches involving Human Subjects.
- 2004年完成我國人體試驗委員會訪查標準及查檢表
  Guidelines and check-list of IRB surveys were established in 2004.
- 於2005年及2007年分別舉辦人體試驗委員會訪查
  IRB surveys have been implemented in 2005 and 2007.

22

Check-list of institution review committee survey

	2005	2007
1	Structure and Composition of IEC/IRB Organization of IEC/IRB and SOP completeness	Structure and Composition of IEC/IRB Organization of IEC/IRB and SOP completeness
2	Legalization of IEC/IRB	Adequacy of IEC/IRB composition
3	Sufficiency of budget and manpower	Sufficiency and suitability of budget and manpower
4	Completeness of review process	Completeness of review process
5	Sufficiency of review process	Sufficiency of review process
6	Sufficiency of risk assessment and research monitoring	Sufficiency of risk assessment and research monitoring
7	Conscientiousness and carefulness on evaluating subject recruitment	Conscientiousness and carefulness on evaluating subject recruitment
8	Conscientiousness and carefulness on evaluating subject privacy protection process	Conscientiousness and carefulness on evaluating subject privacy protection process
9	Maintenance of the informed consent procuring process	Maintenance of the informed consent procuring process
10	Legalization of decision-making process	Legalization of decision-making process
11	Property of monitoring	Property of monitoring
12	Completeness of reviewing and monitoring multicenter research protocols	Completeness of reviewing and monitoring multicenter research protocols
13	Completeness of documentation and archiving	Completeness of documentation and archiving
14	Management of conflicts	(General principle, should be requested in related items)

23

Results of 2007 Survey

- Pass rate: 26/31.
- Those did not pass the survey should not review new cases until improved and pass the re-survey.

- Improvement of IEC/IRBs from 2005 to 2007 :
1. IRB organization constitutions and written SOP.
2. IRB composition.
3. Adequacy of decision making.
4. Adequacy of archiving.

- To be improved :
1. Risk assessment and research monitoring
2. Implement the informed consent procurement

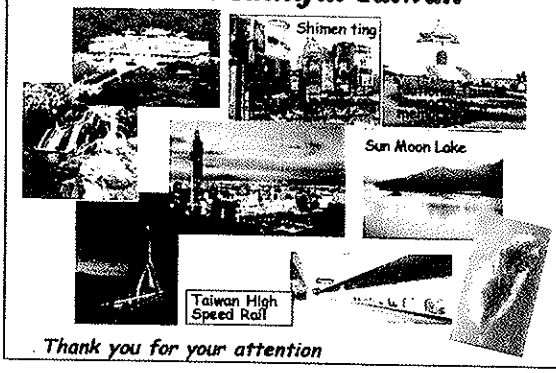
24

Future works

- Keep on quality assurance and improvement on IEC/IRBs of Taiwan.
- Keep on human subject protection education not only to IEC/IRBs but also the public.

25

Formosa - Beautiful Taiwan



Thank you for your attention

26