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Research ethics committees

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Outline

1. Research ethics committees in Japan
2. DoH and research ethics committees
3. Discussions on RECs in 30 years
4. Points to consider in revision of DoH

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Definition

"research ethics committee" (article 15) may include:

1. Committee set by institution
   – Institutional Review Boards (IRBs)
2. Committee in community
   – LRECs, Comité de protection des personnes, State IRBs
3. Centralized committee
   – Central/ Joint IRBs
4. Commercial entity
   – commercial IRBs
5. Others

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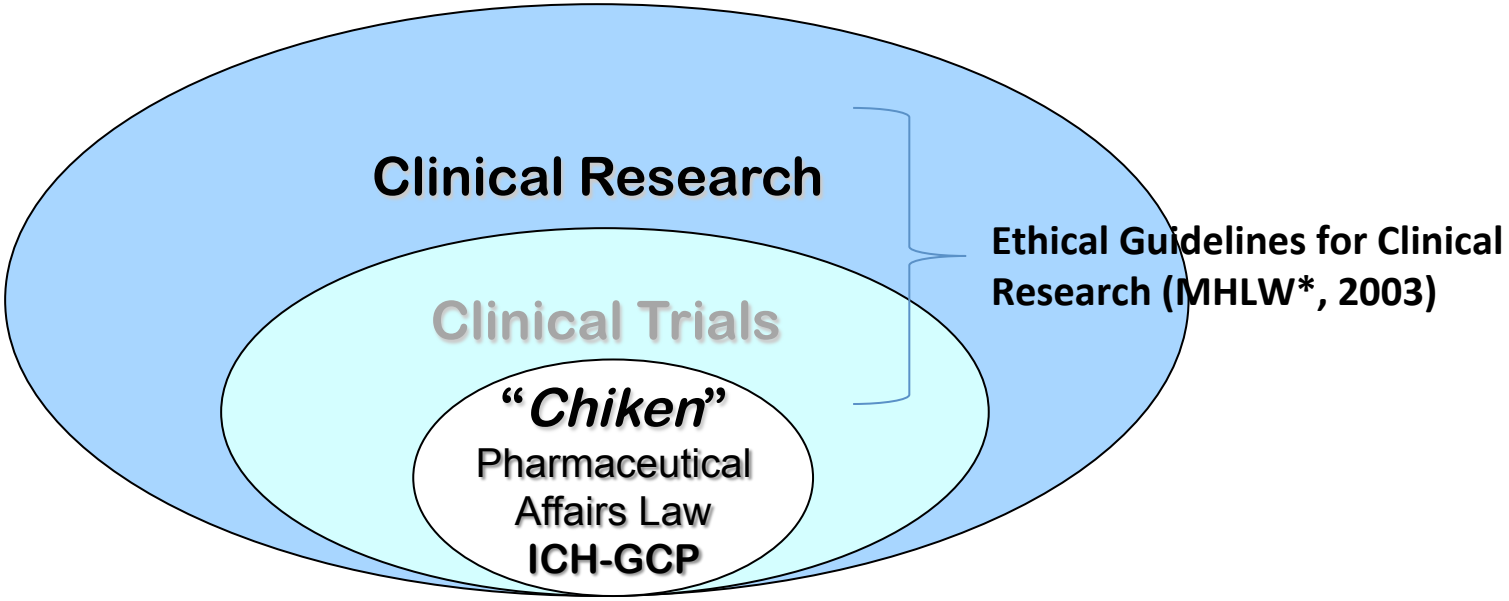
Classification of clinical research in Japan



Clinical Research includes most of clinical trials and observational studies using human samples and/or data derived from individuals

"Chiken" are legally regulated clinical trials, specially intended for collecting evidence for application to the regulative authority (PMDA) for approval of production and sales of drug or medical devices

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Regulation of Clinical Research in Japan: Guideline

Clinical Research	**Ethical Guidelines for Clinical Research (MHLW*)** Ethical Guidelines for Epidemiological Research (MEXT**, MHLW*) Ethical Guidelines for Human Genome/Genetic Analysis Research (MEXT**, MHLW*, METI***)
Clinical Trials	Ethical Guidelines for Clinical Research on Gene Therapy (MEXT, MHLW) Ethical Guidelines for Clinical Research Using Human Stem Cells (MHLW)

* MHLW, Ministry of Health, Labour and Welfare
** MEXT, Ministry of Education, Culture, Sports, Science and Technology
*** METI, Ministry of Economy, Trade and Industry

RECs in Japan

- GCP and all ethical guidelines require to establish REC in each research institution and govern all protocols
- No official registry to cover all RECs. How many? 3,000? (Sasaguri et al, 2008)
- So-called “IRB offices” or “research ethics consultation service” are slightly increasing for quality assurance of RECs
- No original accreditation system
- Central RECs—under discussion

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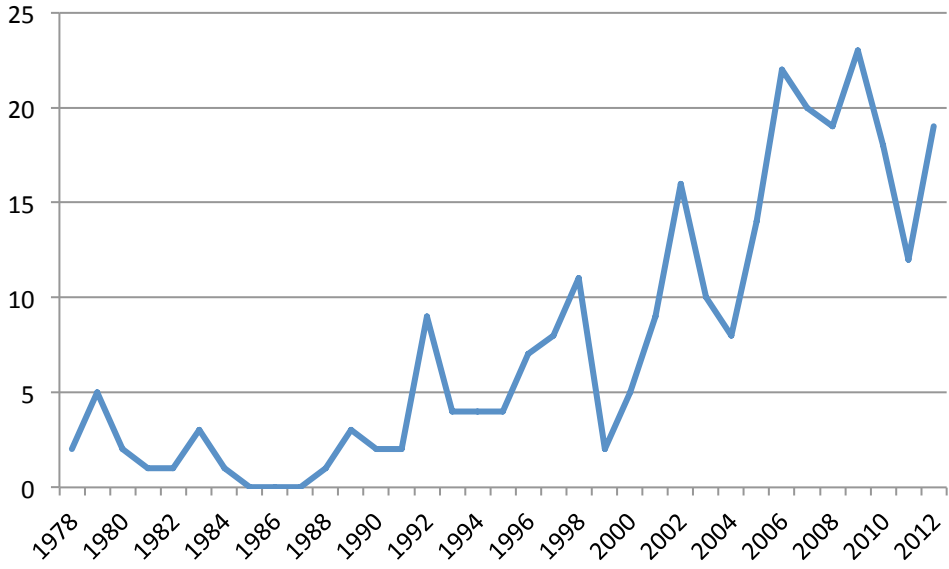
How RECs have been discussed?

- PubMed Search= (institutional review board[Title]) OR (research ethics committee [Title])
- Found 271 papers between 1978-2013
- Most papers from USA; some from Europe, Asia and Africa
- Where to submit?



"IRB" "Bulletin of Medical Ethics" "Journal of Medical Ethics"

"PLoS ONE" "BMC Medical Ethics"

"Journal of Empirical Research on Human Research Ethics"

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30 years ago… 1978-1983

Informed consent in a university hospital Sorensen AA. 1978.

The IRB as deputy sheriff Huff TA. Clin Res. 1979.

The costs of IRBs Brown JH et al. J Med Educ. 1979.

Pharmacists' role Donehew GR et al. Hosp Pharm. 1979.

The responsibility of IRBs Holloway PJ and Worthington HV. J Dent Res. 1980.

The philosophy of IRBs Brown JH et al. J Med Educ. 1980.

The roles of IRBs Bosso JA. Drug Intell Clin Pharm. 1983.

IRB inconsistency Veatch RM. JAMA. 1982.

Ethical issues in nursing research Davis AJ. West J Nurs Res. 1979.

A case study of no-risk decisions in health-related research Gortner SR et al. Nurs Res. 1982.

20 years ago… 1992-93

Pharmacist' role Mutnick AH, Miller LS.1983.

Standards of operation procedures Reynolds MB. 1992; Castronovo FP Jr. 1993; Rosnow RL et al. 1993;

Reflection of activities of IRBs Bartolo.1992;

Readability of consent forms Hammerschmidt DE, Keane MA. 1992.

Understanding IRBs Lovell SL. 1992.

Auditing Cookson JB. 1992.

IRB chair perspectives on ethical issues in phase I oncology research Kodish E et al. 1992.

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10 years ago…2002-03

The cost of the IRBs Humphreys K et al. 2003.

Court decision and IRBs Maloney DM. 2003;

Roles of RECs in follow up Martini N et al. 2003; Suñe-Martin P and Montoro-Ronsano JB. 2003.

Conflict of Interests Weber LJ, Bissell MG.2003.

Variety of review process in minimal risk Hirshon JM et al. 2003.

IRB reform Paasche-Orlow MK, Taggart JC.2002; Mann H.2002; Kornfeld DS.2002; Emanuel EJ.2002.

Research administrators shouldn't serve IRBs Maloney DM. 2002.

Central IRBs Christian MC et al.2002.

Research on stored blood and tissue samples White MT & Gamm J.2002.

Pediatric research Smith DE.2002.

Assessment of the risk/benefit ratio of phase II cancer clinical trials Van Luijn HE et al. 2002

Recent topics: papers in 2011-12

- Need for IRB registry
- Quality assurance
- Quality improvement
- Roles of community IRB
- Conflict of interests
- Who are IRB members?
- Who should be members?
- Successful examples
- Training workshops
- Observation of review process
- Variety of review process in multicenter studies
- Variety of review process in minimal risk
- Variety of review results on surrogate consent

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Recent topics: papers in 2011-12

- Tissue research
- Incidental findings in genome research
- Pediatric drug-trial recruitment
- International research (HIV/AIDS)
- Different views of chairs: data sharing in genetic research
- Anesthesia and informed consent
- Medical education research
- Facial transplantation
- Community-based participatory research

DoH and REC

Tokyo (1975): Protocols 'should be transmitted to a specially appointed independent committee'.

Hong Kong (1989): 'transmitted for consideration, comment and guidance', ' independent of the investigator and the sponsor'

Edinburgh (2000): 'ethical review committee', independent of 'any other undue influence' 'the right to monitor ongoing studies'

Seoul (2008): 'research ethics committee', 'where consent would be impossible or impractical to obtain, the research using identifiable human material or data may be done only after consideration and approval of a REC', 'take into consideration the laws and regulations of the country or countries'

Points to consider in revision of DoH

1. Relationships between DoH and RECs
2. International Research
3. Who should be members?
4. Education for REC chair and members
5. Quality assurance

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1. Relationships between DoH and RECs

- Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.(Article.2)

Should DoH make more recommendations about RECs?

2. International Research

- HIV/AIDS research sponsored by a developed country, but conducted in a developing country conducted in one of four developing countries
- Among papers on PubMed published in 2007 (N = 154) , only 52% mentioned dual approval.
- *"the need for clearer and more universally accepted guidelines"*.

Chin LJ et al. J Empir Res Hum Res Ethics: 6(3):83-91, 2011.

2. International Research

"It [This committee] must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration".(Article 15)

What should RECs in sponsored countries do?

What should RECs in developing countries do?

In cases like global (multi-national) clinical research collaboration?

3. Who should be members?

- No description on requirement on members
- Minimum requirement is “diversity”
  - Age
  - Gender
  - Ethnic background
  - Academic background
  - Patients/participants

Should DoH make any suggestions about members?

4. Training for REC chair and members

"Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications." (Article 16)

- "[…]the report recommends that IRB members and staff complete educational and certification programs on research ethics before being permitted to review research studies" (NBAC 2001)

Should REC chair or members have the appropriate training and qualifications to review new and complicated matters?

Incentives to be trained?

5. Quality assurance

- Accreditation/ recognition system would provide mutually reliable standards to global community.
  - ✓ **USA**: The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
  - ✓ **Asian countries**: AAHRPP and/or The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
  - ✓ **UK**: Accreditation Scheme for the National Research Ethics Service

Should DoH recommend any registry, accreditation or recognition to keep minimum quality of RECs?

Should RECs conduct self-monitoring and improvement ?

Thank you very much for your attention!

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