

研究の監視

倫理審査委員会の持つ重要な役割と研究機関

Research Oversight

The Critical Roles of the Ethical Review Committee (ERC) and the Institution

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臨床研究倫理審査委員会には複数の同義語があります

Interchangeable Names

- IRB: Institutional Review Board*
- IRC: Institutional Review Committee
- ERB: Ethical Review Board
- **ERC: Ethical Review Committee**

* Preferred term in the US
米国で頻用されている用語

研究者の立場に立ってみると

Setting the stage



You are the chief of an Academic Medical Center that has a large human subjects research portfolio.

You are proud of the fact that your research is

- High quality
- Safe
- Ethical

BECAUSE.....

自分の研究が安全で倫理的でもあることが、どうしてわかる？

How do you know it is safe and ethical?



研究の監視には複数の側面があります

Research Oversight is Complex

法的なしばり

- **Regulatory requirements:**

- ERC review and approval
- Grants and contracts
- CT.gov: Registration and results reporting

それ以外

- **Non regulatory requirements**

- Department review and sign-off
- Ancillary reviews; e.g., pharmacy, radiation safety, biomed engineering, etc.
- Training and education of researchers

研究の監視には複数の側面があります

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最終的な責任は全て研究機関に帰します。

The institution is ultimately responsible that all are completed.

日本では機関の長に責任を集約しています

In Japan, Focus on:

Chief Executive of a Research Implementing Entity

The representative of a legal entity, the head of an administrative organ or an individual business owner who carries out research.

Responsibilities:

- Overall supervision of the research
- Arrangement for required systems and procedures
- Approval of the research – in concert with ERC
- Reporting to Minister(s) as necessary

In Japan

日本における研究者の責任は：

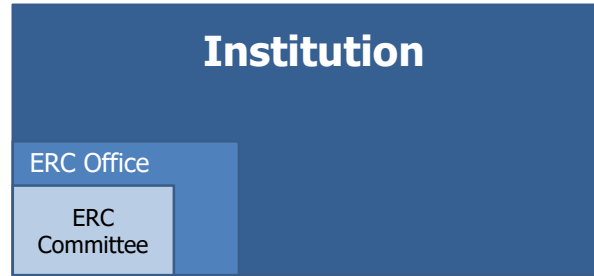
Investigator Responsibility

- Consideration of research subjects
- Ensuring ethical justification & scientific validity
- Education and training

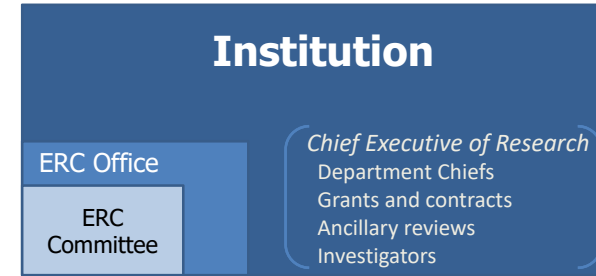
研究責任者(PI)の持つ義務は：

- **Obligations of Principal Investigator**
 - Protocol preparation and compliance of investigators
 - Management and supervision of research progress
 - Following-up research subjects after end of research

ERC and the Institution



ERC and the Institution



機関内 ERC

ERC and the Institution



機関内 ERC

ERC review: ethical and scientific Bad science = bad ethics

- **Scientific or scholarly review** to ensure that:
 - (1) Risks are minimized: (i) sound research design and (ii) if possible use procedures already being performed for diagnostic or treatment purposes.
 - (2) Risks are reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result.

» US Regulations 45 CFR 46.111(a) and 21 CFR 56.111(a)

科学面の審査で吟味されるべき内容は

Scientific Review Includes

- Study team has expertise and time
- Appropriateness of the Proposed Study Design:
 - Objectives are scientifically sound
 - Study can meet the objectives with clear endpoints
 - Patient populations and inclusion/exclusion criteria are well defined
 - Appropriate sample sizes and statistical design

ERC審査の種類

ERC review: Different approaches

機関内ERC

- Local ERC
 - “Your institution’s ERC”

機関外ERCへの審査委託

- Cede review to an external ERC
 - Another academic medical center
 - Research center
 - Commercial/independent ERC

外部ERCへの審査委託の増加傾向には背景が：

Increase in Cede Review

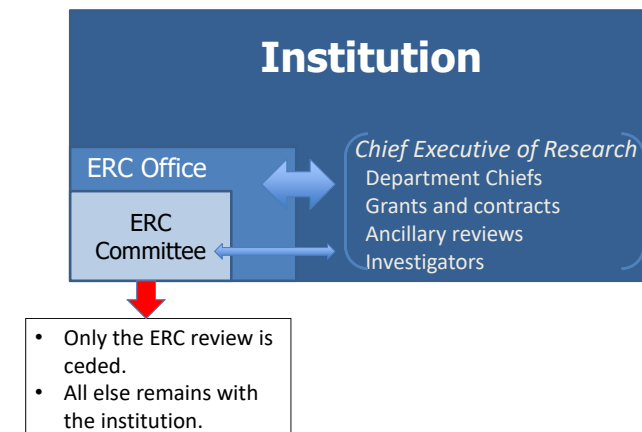
審査を一つのERCに限る傾向が出てきた・・・

- Mandates for use of a single ERC (sERC) for multi-site research
 - Industry sponsors
 - May limit participation to those willing to use a sERC
 - NIH Policy
 - January 25, 2018
 - Multi-site domestic (U.S.) research funded by NIH must be reviewed by a sERC
 - Revised Common Rule (US Regulations)
 - Multi-site domestic research regardless of funding must be reviewed by a sERC

しかし、その場合も責任は研究機関にあることを忘れずに。

BUT remember...

Institutional responsibilities remain with the Institution



機関内ERCの長所と短所

Local ERC Review

長所

Advantages

- Ease of communication with institutional requirements
- You know your investigators
- You know local research infrastructure

短所

Disadvantages

- Cost
- Do you have enough research to keep the ERC busy?
- Maintaining adequate expertise
- Conflict of interest issues

しかし、考えておかなければならないことは：

Consider...

- The following protocols are submitted
 - Intranasal ketamine for depression in children
 - Use of methotrexate in coronary artery disease
 - Nursing study comparing different discharge plans
- Your ERC membership
 - Lawyer
 - Minister
 - 2 MDs (general surgeon and retired internist)
 - PhD in microbiology

しかし、考えておかなければならないことは：

Consider...

あなたの機関内にあるERCは適切な審査ができる能力をお持ちですか？

- The following protocols are submitted
 - Intranasal ketamine for depression
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Can your ERC perform an adequate review?

私共 Partners HealthCareという組織は、大規模合同機関内ERCとも言うべきものです。

What we have done at Partners HealthCare A 'large multi-institutional local' model

- What is Partners?
- The old 'routine' model
- The current model

Boston



Boston



Multiple Medical Schools



Boston

市内に在る3つの医学部



Multiple Medical Schools



- Dana Farber Cancer Institute
- Boston Children's Hospital
- Beth Israel Deaconess
- Cambridge Health Alliance
- Harvard Pilgrim Health
- Hebrew Senior Life
- Joslin Diabetes
- Judge Baker Children's Center
- Mass Eye and Ear Institute
- Mt. Auburn
- Scheper's Eye Research Institute
- VA Boston Health Care System
- Massachusetts General Hospital (MGH)
- Brigham and Women's Hospital (BWH)
- McLean Hospital
- Spaulding Rehabilitation Hospital
- Faulkner Hospital
- Newton-Wellesley Hospital
- North Shore Hospital
- Cape and Islands Hospital

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それぞれが独自性を保つものは

Separate

- Legal entities
- Funding recipients
- Research Leadership

Partnersの設立によって生じた違いは：

The Change

- Massachusetts General Hospital (MGH)
- Brigham and Women's Hospital (BWH)
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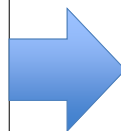
7 Separate IRBs

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7 Separate IRBs



One Single IRB System

ここまでに至る過程では：

How we got here

- Central leadership endorsement and communication
- Planned and ongoing centralization of other functions (e.g., grants and contracts)
- Created 7 ERCs to handle the number of protocols
 - 13 meetings/month
 - 9,489 active protocols

Partnersの存立に要件となっているものは：

Important Ingredients

- Clear understanding of ERC authority
- Development of single set of policies and procedures
- Single (ultimately electronic) submission system
- Process for coordinating and communicating with each hospital re: institutional responsibilities
- ERC panels populated by representatives from each of the hospitals
- Adequate staffing

Partnersの活動状況を数値で表すと

Metrics: 2017

Activity	Number	Full Board	Expedited
Initial review	2,528	16%	84%
Continuing review	6,432	13%	87%
Other events	1,362	5%	95%
Amendments	6,725	4%	96%
Study Staff Amendments	15,035*		

Current active protocols = 9,489

* All administrative review

Partnersによって私どもは、科学面の審査に必要な専門家集団を形成することができました。：

We have large panels to meet The Importance of scientific expertise

- **Bad science → bad ethics**
科学面が劣悪であれば、倫理的にも劣悪なのです。

実際、専門家集団としての層の厚さを数字で見ると・・・

Scientific 'depth' of large panels

MD Expertise	Panel 1	Panel 2
Internal Medicine	16	20
Neurology/Psychiatry	4	7
Surgery (neuro, ortho, ENT, peds, gen'l)	4	4
Radiology	3	3
Emergency physicians	3	3
Anesthesia	2	2
Pediatrics		2
Ob-Gyn	1	
Nuclear Medicine	1	

Note:

- Both panels have 31 'seats' with true quorum of 16
- Require at least 24 to hold the meeting (accounting for recusals, being called out)
- System of alternates: 2 or 3 people cover 1 'seat'

要約
In Summary

- ERC review is critical – but NOT the only oversight
- ERC review can be local or external
- Institution remains responsible that all oversight is completed
- Bad science – bad ethics



質問をお受けします

Questions?