What Hospital and Healthcare System Compliance Officers Need to Know When Relying on an External Institutional Review Board (IRB)

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The Journey

Introduction
Regulation and the Role of the IRB
Recent and Upcoming Regulatory Change re: single, external IRB
Selecting an external IRB
Documenting and Managing the Division of Responsibilities
Questions and Answers
Disclaimer

- Personal experience is limited to systems where the doctors are employees or have an exclusive relationship.

Institutional Review Board (IRB)

- Review board composed of
  - scientists and non-scientists
  - affiliated and non-affiliated
- Responsible for the protection of human subjects of research by ensuring that (regulated) research protocols are consistent with ethical standards and compliant with regulatory and statutory requirements
- The IRB has the authority to approve, disapprove, or require modification to a research protocol in order to secure approval
- If the IRB disapproves a research protocol, the institution can not approve the protocol
Regulations Assigning Responsibilities to IRBs

- **Protection of Human Subjects (federally funded research)**: 45 CFR 46
  - Common Rule Depts & Agencies

- **Food and Drug Administration (drugs, devices, biologics)**: 21 CFR 56

- **HIPAA Privacy Rule (protected health information)**: 45 CFR 164.512(i)

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Traditional, Local IRB Review

- **Research Sponsor Funds/Selects an Institution**
- **IRB Reviews the protocol for implementation at that institution**
- **IRB approval is gatekeeper for institutional approval**

- Regulatory requirement for IRB membership ensures the IRB has the expertise to review the protocol
- Institutional Official appointment of the IRB members and organizational relationship with IRB staff, ensures IRB approval meets institutional requirements
- Institution owns all parts of the system (i.e., IRB, investigators, institution) and all risk
What problem is the regulatory change fixing?

- Personalized/Precision Medicine (clinical trials)
- Health Disparities (target populations)
- Translational Research (outcomes)
  - Electronic medical records
  - HITECH Meaningful Use

Research is Changing → Multi-Site, Big Data, Personalized
More sites, fewer people per site

UNDERSTANDING PRECISION MEDICINE

In precision medicine, patients with tumors that share the same genetic change receive the drug that targets that change, no matter the type of cancer.

FDA Approves Two Genomic Profiling Tests for Cancer
Tests can identify different cancer-associated genetic alterations.

Using the genetic changes in a patient’s tumor to determine their treatment is known as precision medicine.
Credit: National Cancer Institute
The future of health begins with you

The All of Us Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.
More sites, fewer people per site…

**Tendency toward an iterative review process**

Regulatory Change Effective 1/19/2019

- New language at § ___101(a) gives Common Rule departments and agencies the authority to enforce compliance directly against IRBs that are not operated by an assured institution.

Prior: enforcement authority was limited to the institution(s) where the research was being conducted – even if the IRB was at fault, not the institution.
Regulatory Change Effective 1/19/2020

- New requirement at § ___1.114 that a single IRB be responsible for certain multi-institutional clinical trials, also described as cooperative research.

Scope: This requirement only applies to research activities that are federally funded. It is not applicable to activities solely regulated by the FDA.

However, it seems likely that sponsors of FDA regulated clinical investigations may want to transition as well.

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Single, External IRB Review

Coordinating Center: Master protocol

IRB

Institutional Approval

Institutional Approval

Institutional Approval
Impact: Institutions without an internal IRB

Typical Use of an IRB

- Expanded Access
  - Access to investigational medical products for patients with life-threatening or serious disease or condition outside of a clinical trial
  - MD is “sponsor-investigator”
  - Does not include “pay to participate” in research*
- Humanitarian Use Devices
  - FDA approved, but less stringent standard
- Meaningful Use “Research” (?)

Mostly Good News

- Accountability
- Review type fits the regulatory structure
- Robust Nat'l guidance
- Focus is FDA and clinical trials

*The Right to Try Act signed into law May 30, 2018 – bypasses FDA oversight, and IRB review is not required. Patient initiates the request for Phase I.

Impact: Institutions with an Internal IRB

Typical Use of an IRB

- Review research protocol for the institution
  - Federal: Common Rule/FDA/ HIPAA
  - Investigator initiated
- Knowledge of “local” issues
  - State and local laws
  - Institutional requirements
  - Subject population characteristics
- Gatekeeper for the institution
  - Knowledge of local capabilities
  - Ensure investigator training
  - Ensure investigator licensing and credentials

Mixed News

- Accountability is split between IRB and institution
- Document Local information for use by external IRBs – many IRBs
- Scope mismatch
- IRB workload down
  Institution workload up
Selecting an sIRB

Institutional sIRB Review Worksheet/Checklist (handout)

- Selecting an sIRB
  - Registered with US Department of Health and Human Services, Office of Human Research Protections (Summary)
  - Quality Standard (Q1)
  - Expertise Standard (Q2)

Documenting the Arrangement

Institutional sIRB Review Worksheet/Checklist (handout)

- Reliance Agreement
  - Signatory (Q3)
  - Point of Contact (Q3)
  - Scope (Q4 and Q5)
  - Communication plan
Managing the Division of Responsibilities between Reviewing IRB and Relying Institution

IRB (research protocol)
- Review the research protocol to ensure it complies with
  - the ethical guidelines and regulatory requirements for involving humans
  - local context (understanding the subject population)
  - good science
- Approve, disapprove or require modification to the protocol in order to secure approval

Institution (people)
- Identifying and providing local considerations for the IRB
- Contractual agreements
- Institutional approval(s)
- Investigator licensing, credentials and training
- Oversight of the research (controls)
- Responsibility for the subjects
- FCOI/COI Management

Questions?