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

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Disclaimer

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

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Institutional Review Board (IRB)

- Review board composed of
  - scientists and non-scientists
  - ~~affiliate~~d 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

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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

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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

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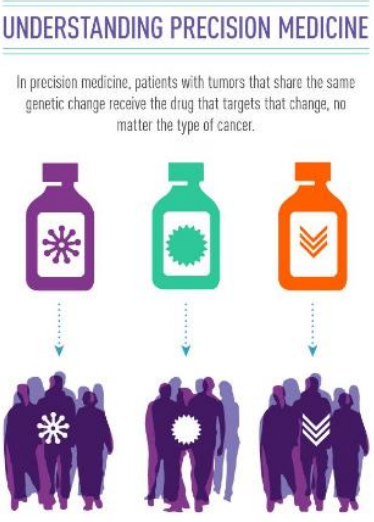

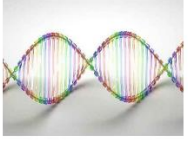

FDA Approves Two Genomic Profiling Tests for Cancer

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

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NIH National Institutes of Health
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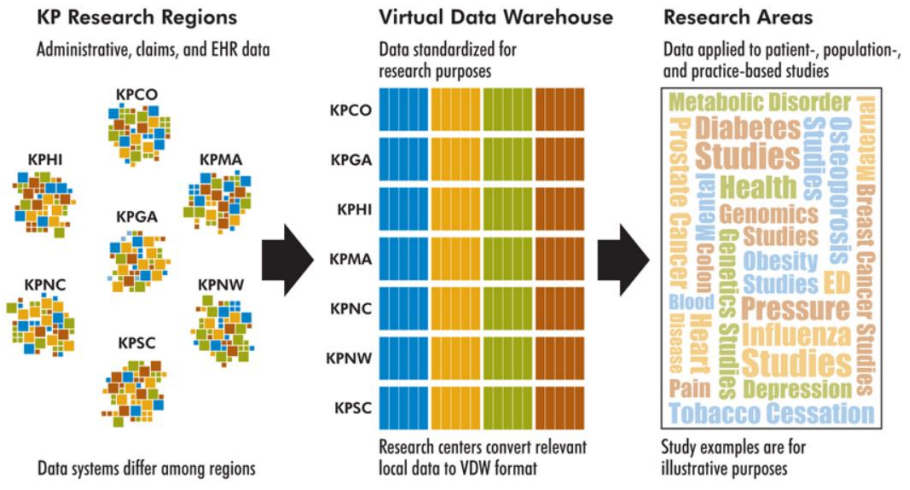

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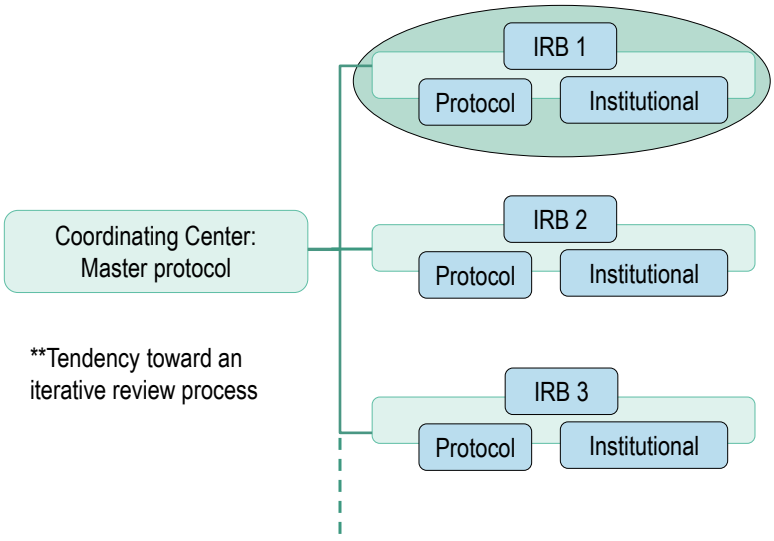
More sites, fewer people per site…



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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.

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Regulatory Change Effective 1/19/2020

- New requirement at § ___.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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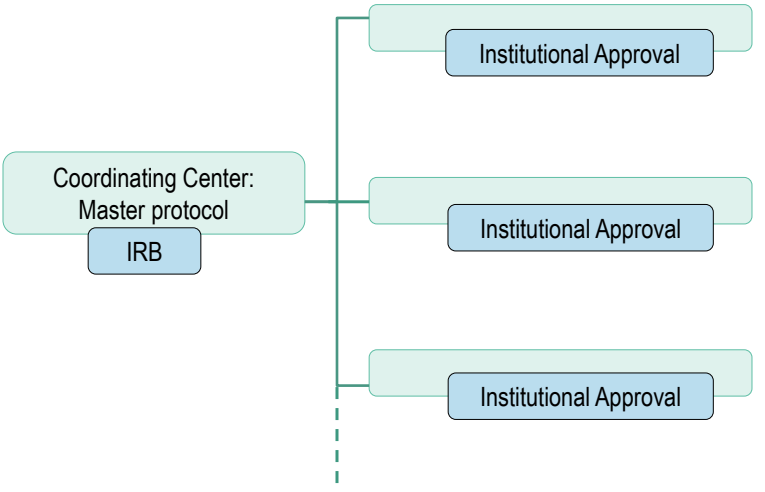
Single, External IRB Review



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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.

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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

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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)

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Documenting the Arrangement

Institutional sIRB Review Worksheet/Checklist (handout)

- Reliance Agreement
  - Signatory (Q3)
  - Point of Contact (Q3)
  - Scope (Q4 and Q5)
  - Communication plan

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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

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Questions?

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