

Central Ethics Committees

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Models for Ethics Committees

- Institution based – each ethics committee is in an institution that performs research.
 - Example - China.
- Central – the ethics committee is an independent organization separate from an institution. Can be government run or private.
 - Example – Denmark.
- Mixed – Combination of both models.
 - Example Brazil.

United States

- The US started in the 1960s on an institution based model.
- Moving steadily from an institution model to a central model:
 - NIH Policy
 - New Rule
 - 21st Century Cures Act

NIH Policy

- National Institutes of Health (NIH) policy on single IRBs.
- Effective September 2017.
- All NIH-funded multi-site trials in the US must use a single IRB.
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

The New Rule

- First major change to the US human subject protection regulations since 1981.
- Adopted by 17 federal agencies.
- Among many other changes, requires single IRB review of multi-site research funded by the agencies.
- Effective January 2020.
- <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

21st Century Cures Act

- New Congressional law.
- Strongly encourages use of central IRBs.
- Requires the FDA to harmonize its policies with the final rule.
- Industry funded studies in the US are already usually under a central ethics committee, this will increase that trend.
- <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>

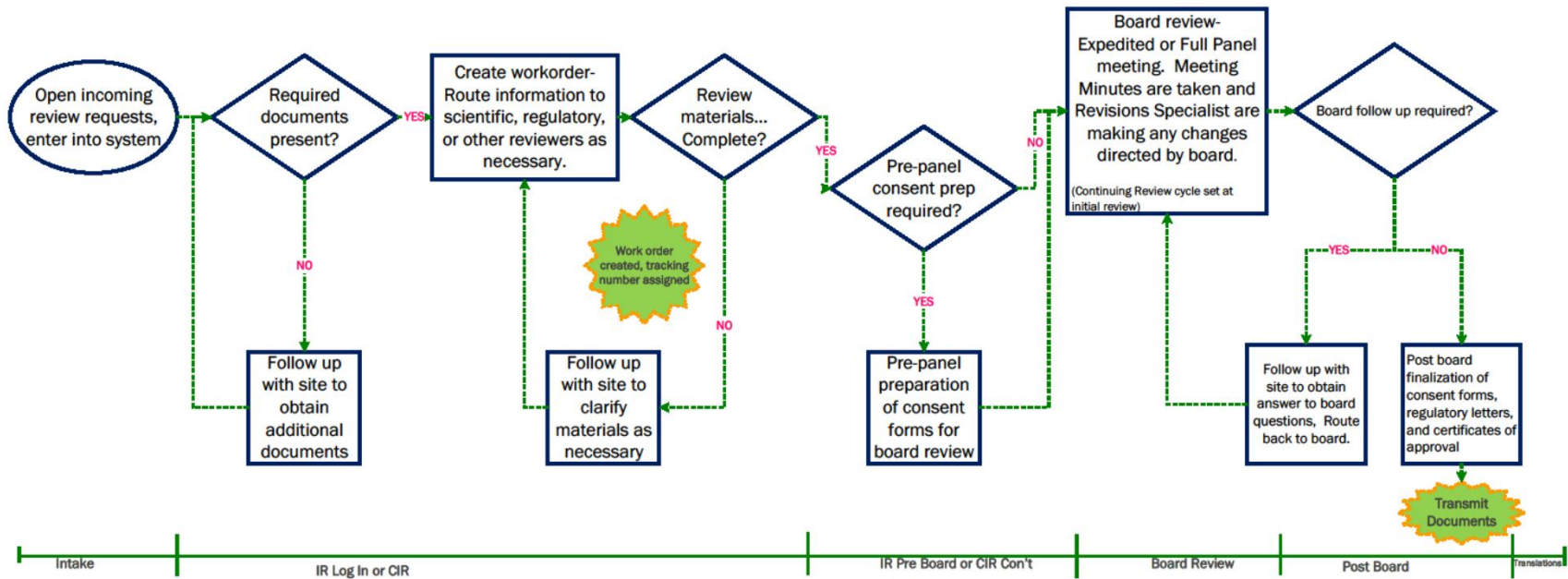
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- Eleven ethics committees located across the United States.
- 2 or 3 meetings every day.
- Approximately 200 ethics committee members, 80% unaffiliated with the committee.
- Just under 400 employees providing support for the committees.

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- Overseeing approximately 10,000 open protocols.
- Overseeing approximately 41,000 Investigators.
- Review research for 2,300 institutions, ranging from small community hospitals to academic medical centers like Harvard.

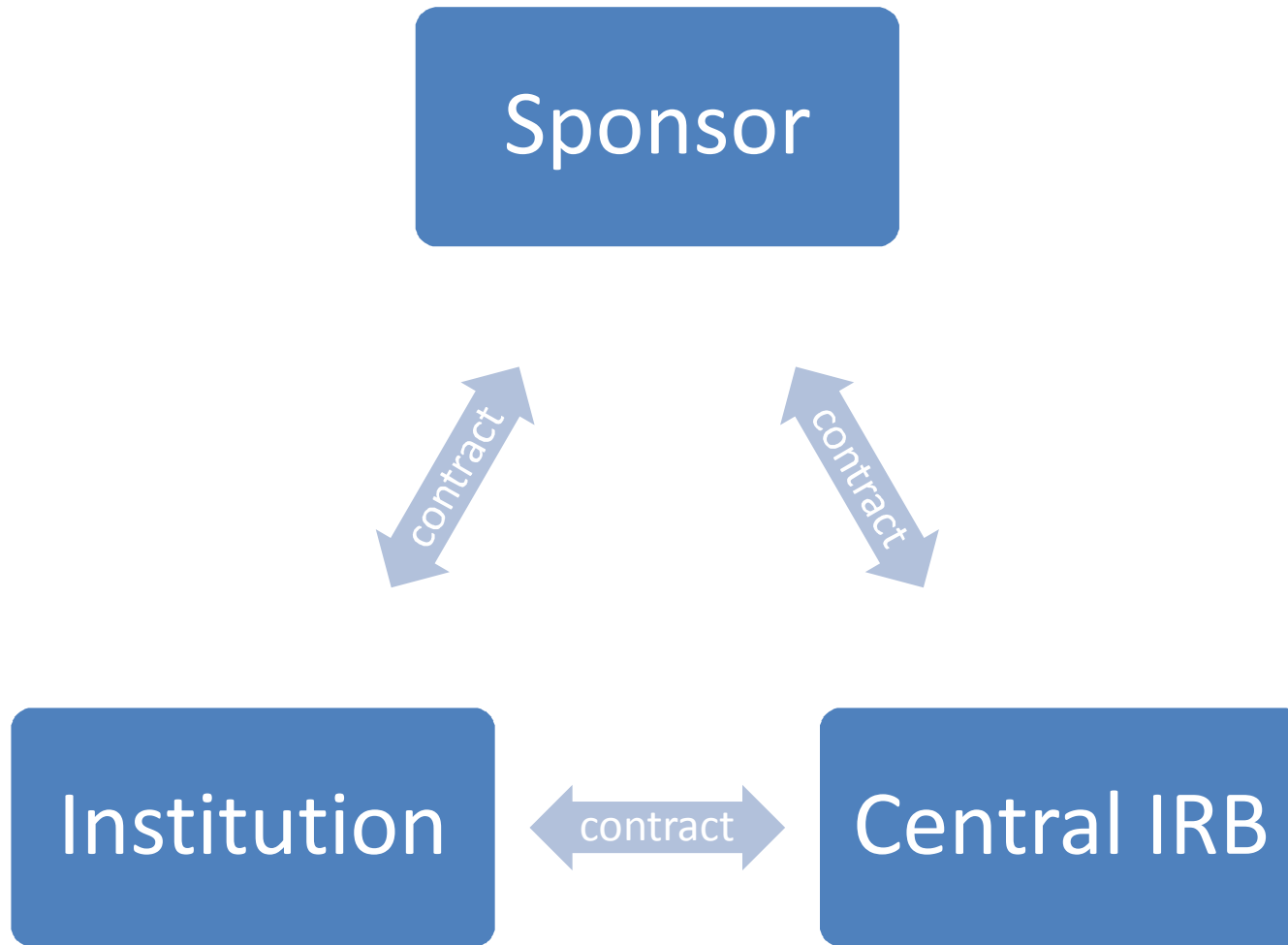
Work Flow



Types of Sites

- Sites vary from a single physician in a private office to Academic Medical Centers like Harvard.
- For a small site easy to use a central ethics committee.
- The Academic Medical Centers are outsourcing their research to central ethics committees or forming their own central committees.

Contracts Among Multiple Parties



Steps for an Institution to Use a Central IRB

- Establish a Written IRB Authorization Agreement, which can vary from a one page to a 30 page document.
- “Mesh the bureaucracies” and determine which organization will take on which required duties. Examples include:
 - Which studies are outsourced to the central committee
 - Points of contact and communication flow
 - Evaluating investigator qualifications
 - Receiving subject complaints
 - Determining education requirements
 - Conflict of interest reviews

Steps Continued

- Interpret state law
- HIPAA requirements
- Harmonization with other committees, such as Institutional Biosafety Committee (IBC)
- Template consent form language requirements
- Investigating allegations of non-compliance
- Reporting to agencies of serious or continuing non-compliance, suspensions, terminations, and unanticipated problems
- Etc.

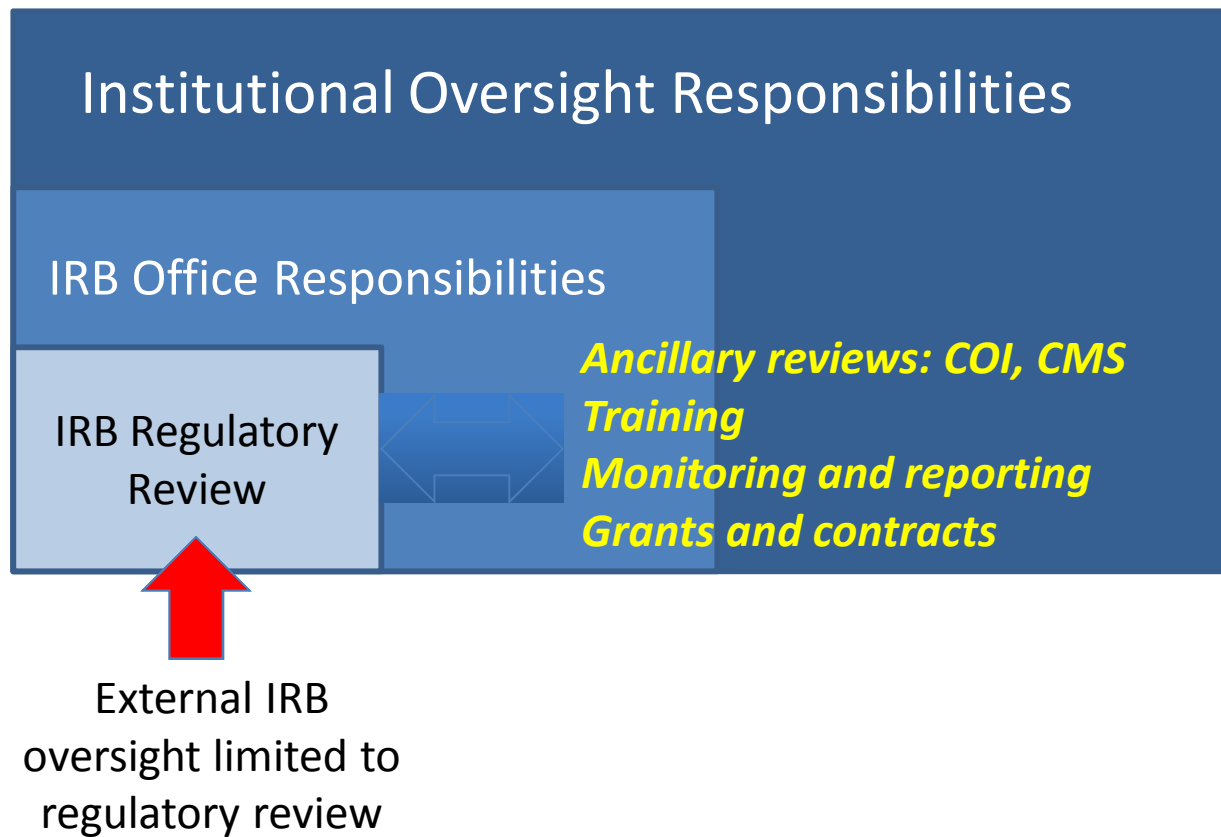
IRB vs Institution



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Questions?